IAVI DATA WAREHOUSE
Data User Application and Agreement

This Data User Application and Agreement (this “**Agreement**”) is entered into by and between the “**Recipient**” and “**Recipient Institution**” named in the signature page hereof, on the one hand, and **International AIDS Vaccine Initiative, Inc.** (**“IAVI”**), on the other hand,effective as of date of the IAVI’s signature hereof under the procedure set forth below.

**BACKGROUND**

IAVI and its research partners and collaborators have created and implemented a digital repository (the “**IAVI Data Warehouse”**) to collect, assemble, and manage data obtained in the course of conducting clinical trials (collectively, “Data”), which trials involve the collection and analysis of human donor samples. The Recipient and the Recipient Institution would like access to certain of the Data for the research purposes set forth herein.

This Agreement sets forth the scope and terms and conditions under **IAVI** agrees to grant access to the Data to Recipient and the Recipient Institution.

**APPLICATION**

1. The Recipient and the Recipient Institution hereby apply for the use of the Data by completing the application section of this Agreement below and executing and submitting this Agreement to IAVI for approval online at dataspace.iavi.org (“IAVI DataSpace”).
2. IAVI will submit this Agreement for consideration of the application made hereunder by a committee associated with the IAVI Data Warehouse. Upon approval by such committee, IAVI will execute this Agreement, whereupon this Agreement will be effective as between the parties effective as of IAVI’s signature date.
3. Upon the effectiveness of this Agreement, IAVI agrees to provide to the Recipient and the Recipient Institution the Data requested on the Application submitted as part of this Agreement.
4. In signing this Agreement, the Recipient and the Recipient Institution agree to comply with the Terms and Conditions of Data Access as in effect from time to time (“**Terms**”). Such Terms are posted online on IAVI DataSpace and a copy of such Terms are attached hereto and incorporated herein.

[*Application form follows*.]

**Research Project:** [INSERT TITLE OF PROPOSED RESEARCH PROJECT]

**Data Requested:**

[Please provide a detailed description of data requested]

**Start Date of the Research Project**: [Insert research project start date]

**End Date of the Research Project**: [Insert research project end date]

**Research Project Narrative Summary (maximum 250 words):**

Provide a concise description of your proposed research project and its expected outcome(s).

Please use plain English that is suitable for a non-specialist audience.

Click or tap here to enter text.

**Your Proposed Research Project (maximum 700 words):** *Please list the aims and specific objectives of the proposed research project. How will the project contribute to the IAVI’s mission of translating scientific discoveries into affordable, accessible public health solutions? Please ensure that the scientific purpose is clearly described, specifying the approach and methods to be used, with details of the analysis to be performed. What is the importance and relevance of the proposed activities?*

Click or tap here to enter text.

**Project milestones and deliverables (maximum 350 words)** *Provide clearly delineated milestones with expected dates for achieving those and corresponding deliverables for the project (up to five).*

Click or tap here to enter text.

**Dissemination plan for research results (maximum 700 words)** *Provide an estimate of analysis completion date, how the data will be exploited and/or shared/made accessible for verification and re-use (anticipated date of manuscript submission for publication, and date research results are made available to the IAVI DataSpace).*

*Please give details of your plans to store, manage and share the data and knowledge that will be generated by this project. When giving details of your plans, take into consideration:*

*The nature of the data that will be generated/collected and how it will be curated and preserved*

*The value of the data to other researchers. Details of the data ownership, any limits to the data sharing, for example to protect study participants or intellectual property, must be provided.*

Click or tap here to enter text.

**Bibliography**

[Provide references for all cited material. References should be listed in Vancouver style]

Click or tap here to enter text.

[*Signature page follows.*]

Each of the undersigned agrees to the terms of this Data User Application and Agreement and the Terms and Conditions of Data Access and to be bound by them.

**Recipient Institution**: Click or tap here to enter text.

Address: Click or tap here to enter text.

Click or tap here to enter text.

Click or tap here to enter text.

Click or tap here to enter text.

Signature: By:

Name: Click or tap here to enter text.

Title: Click or tap here to enter text.

Date:Click or tap to enter a date.

**Recipient**: Click or tap here to enter text.

Name: Click or tap here to enter text.

Title:Click or tap here to enter text.

Date:Click or tap to enter a date.

**Data Access Application Approved by IAVI**

International AIDS Vaccine Initiative, Inc.
IAVI Data Warehouse

125 Broad Street, 9th floor

New York, New York 10004

Signature: By:

Name: Click or tap here to enter text.

Title: Click or tap here to enter text.

Date:Click or tap to enter a date.

**Schedule to Data User Application and Agreement**

**List of Authorized Users**

Please list all individuals who will have access and use of the Data and their affiliation.

|  |  |
| --- | --- |
| Authorized User Name and Title | Affiliation |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap to enter a date. | Click or tap to enter a date. |
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***IAVI Data Warehouse***

***Terms and Conditions of Data Access***

These Terms and Conditions of Data Access (these “**Terms**”) are incorporated into and form part of the Data User Application and Agreement (the “**Data User Agreement**”) to which these Terms are attached. In the event of any inconsistency between the Data User Agreement and these Terms, the terms of the Data User Agreement shall prevail.

**PURPOSE OF THE IAVI DATA WAREHOUSE**

IAVI administers various research programs worldwide to advance research in the biological sciences, including in the fields of infectious and non-infectious diseases with the support of various foundations and governmental and non-governmental organizations. The research involves the accumulation of data derived from clinical trials and from the collection and analysis of human donor samples, which data is used to support ongoing and future research.

IAVI and its research partners and collaborators have created and implemented a digital repository (the “**IAVI Data Warehouse”**) to collect, assemble, and manage data derived from clinical trials and the collection and analysis of human donor samples (collectively, “**Data**”). As used herein, the term “**Data**” includes data deposited into the IAVI Data Warehouse as well as data generated from any data deposited in the IAVI Data Warehouse. Depositors of Data into the IAVI Data Warehouse are referred to herein as “**Data Producers**”.

**Terms and Conditions:**

1. Data are provided to the Recipient and the Recipient Institution on a non-exclusive basis. Each Data Producer is obligated to assure that the Data have been obtained in accordance with all relevant laws and guidelines and that the Data have been obtained from human donors that have given their consent for their Data to be used for research purposes.
2. The Recipient and the Recipient Institution agree: (i) to use the Data solely to conduct the research project that is described in the Data User Agreement and approved by IAVI (as approved, the “**Approved Research Project**”), (ii) to conduct the Approved Research Project in the manner and timeframe set out in the Data User Agreement, (iii) to use the Data in accordance with the terms of the Data User Agreement and these Terms and all applicable laws, regulations, and all applicable professional, academic and institutional standards, and (iv) to hold IAVI harmless from all losses, liabilities, actions, claims, proceedings, demands, and any associated costs that may arise (whether directly or indirectly) arising out of any breach of the foregoing.
3. The Recipient and the Recipient Institution may apply for the use of Data for additional research projects by completing additional Data User Agreement(s), which upon approval by IAVI will incorporate and be governed by these Terms.
4. The Recipient and the Recipient Institution must notify IAVI prior to making any significant change(s) to the Approved Research Project. Modifications will be reviewed and approved by IAVI, which approval shall not be withheld unreasonably.
5. After the Recipient has received the Data agreed for the Approved Research Project, IAVI will be entitled to publish on its website:
	1. The summary of the Approved Research Project contained in the Data User Agreement (with the exception of any material that the parties have agreed would be kept confidential); and
	2. Summary details of the Recipient and the Recipient Institution (unless it has been agreed by the parties to the Data User Agreement that this information would be kept confidential).
6. The Recipient and the Recipient Institution agree to preserve the confidentiality of the Data. They agree not to undertake, use, or attempt to use the Data to compromise or otherwise infringe upon the confidentiality of personal information of the human donors. Moreover, the Recipient and the Recipient Institution agree not to link or combine the Data provided under the Data User Agreement to other information or other data available to them in a way that could identify the human donors. The Recipient and the Recipient Institution agree to protect the confidentiality of human donors in any Publications (as defined in Section 9.a.) that they prepare by taking all reasonable care to limit the possibility of human donor identification.
7. The Recipient and the Recipient Institution agree not to transfer or disclose the Data or any copies thereof, in whole or part and in any medium, to anyone not listed in the Data User Agreement without permission in writing from IAVI.
8. The Recipient and the Recipient Institution acknowledge that IAVI is responsible only for the collection, funding and protection of the Data and that IAVI:
	* + 1. Makes no warranty or representation, express or implied, as to the accuracy, quality or comprehensiveness of the Data;
			2. Disclaims--and Recipient and Recipient Institution excuse and waive--to the fullest extent permitted by law, all liability for actions, claims, proceedings, demands, losses (including but not limited to loss of profit) and any associated costs made against the Recipient or the Recipient Institution that may arise (whether directly or indirectly) in any way whatsoever from the Recipient’s use of the Data or from the unavailability of, or break in access to, the Data for whatever reason; and
			3. Bears no responsibility for the further use, analysis or interpretation of the Data.
9. The Recipient and Recipient Institution are required to use their best endeavours to publish the findings of any research involving the use of the Data in an academic journal or on an open source publication site within 12 months after the earlier of the projected completion date of the Approved Research Project (as specified in the Data User Agreement) or the actual completion date. In furtherance of the foregoing:
	1. The Recipient and the Recipient Institution shall provide to IAVI a copy of each proposed manuscript, article, presentation or other publication of the results of the Approved Research Project (each a “**Publication**” and collectively, “**Publications**”) at least thirty (30) days prior to submission to allow IAVI or the relevant Data Producer (i) to preserve its intellectual property rights or the intellectual property rights of its other collaborators by submitting in advance of such Publication appropriate intellectual property filings and (ii) to remove its copyrighted and/or confidential information and of its collaborators (with such actions not taking longer than an additional 60 days after the initial 30 days review period) and to offer comments and suggestions, such comments and suggestions to be considered in good faith.
	2. The Recipient and the Recipient Institution shall recognize in each Publication: (i) the contribution of the Data Producer(s) and their respective collaborator(s) and funders, (ii) the role of IAVI in managing the IAVI Data Warehouse, and (iii) the funding of the IAVI Data Warehouse by the USAID and any other applicable funder.
	3. The Recipient and the Recipient Institution agree to provide IAVI copies of any Publications that include Data for dissemination as part of IAVI’s mission.
10. Ownership of any invention made from the use of the Data shall follow inventorship, subject, however, to any rights to inventions not waived by the relevant Data Producer. The Recipient and the Recipient Institution are responsible for obtaining the relevant consents from any such Data Producer. For use of the Data, the Recipient and Recipient Institution agree to grant IAVI a world-wide, royalty-free, fully paid-up, non-exclusive, license (with full rights to sublicense and to assign) for non-commercial research for any invention made from the Data. The Recipient and the Recipient Institution may use the Data to make intellectual property claims for any inventions belonging to them that arise out of the Approved Research Project, subject to any rights to inventions not waived by the relevant Data Producer.
11. The Recipient and the Recipient Institution acknowledge and agree that their use of Data in all Approved Research Projects and all data and results arising out of such research are subject to general principles of global access as required by USAID and other funders. Accordingly, subject to the publication requirements hereunder, the Recipient and Recipient Institution will each timely share with the public the results and data arising out of any Approved Research Project that uses the Data and will make available any product-related invention to provide health solutions for the benefit of people in the developing world (low income and low-middle income countries as defined by the World Bank) at affordable prices and in reasonable quantities.
12. The Recipient and the Recipient Institution will notify IAVI as soon as they become aware of a breach of the terms or conditions of the Data User Agreement or these Terms.
13. IAVI reserves the right to terminate the Data User Agreement immediately in the event of a breach by the Recipient, or the Recipient Institution or any other user authorized by Recipient Institution. Upon termination or otherwise upon conclusion of the Approved Research Project, the Recipient and the Recipient Institution will be required to destroy any Data held, including copies and backup copies thereof unless obligated to retain the Data for archival purposes in conformity with applicable law. Any Data which are not destroyed shall remain subject to the terms of the Data User Agreement and these Terms.
14. The Recipient and the Recipient Institution agree and covenant that Data shall be accessible only to the Recipient and other users who have been authorized in writing to access Data. Data will be handled, made accessible, stored and protected in accordance with the Recipient Institution’s standard security measures and in all cases in accordance with the highest standards for the safeguarding of human biological data for institutions of the type to which the Recipient Institution belongs.
15. Within the shorter of 6 months of publication or 12 months of when the Approved Research Project was to be completed, the Recipient is required to provide the results of the Approved Research Project, and any other data generated from Data, for inclusion in the IAVI Data Warehouse in such detail and format as IAVI reasonably requires. IAVI will give reasonable consideration to written requests (containing an appropriate explanation) for an extension of these time limits. IAVI agrees to treat the report and all information, data, results, and conclusions contained therein as confidential information belonging to the Recipient and the Recipient Institution until the results and/or data from the Approved Research Project are published.
16. The Recipient and the Recipient Institution shall not use the name or logo of IAVI or the IAVI Data Warehouse or any personnel in any marketing or other publication, without first obtaining the written consent of IAVI.
17. Nothing in the Data User Agreement or these Terms shall create, imply or evidence any partnership or joint venture between the parties or the relationship between them of principal and agent. No party has the authority to make any representation or commitment, or to incur any liability on behalf of the other and each party shall be severally liable for any breach of the Data User Agreement or these Terms.
18. The obligations of the Recipient and the Recipient Institution under these Terms and under the Data User Agreement of which these Terms are part may not be assigned by either such party without the prior written consent of IAVI, which consent shall not be withheld unreasonably. These Terms and the Data User Agreement(s) of which these Terms are part maybe assigned by IAVI by giving written notice of such notice to the Recipient and the Recipient Institution
19. These Terms and the Data User Agreement of which these Terms are part (and any dispute, controversy, proceedings or claim of whatever nature arising respectively therefrom) shall be construed, interpreted and governed by the laws of the State of New York, USA and shall be subject to the exclusive jurisdiction of the New York courts.
20. These Terms are subject to revision from time to time effective upon notice of the revised terms and conditions to the Recipient and the Recipient Institution by IAVI. The revised terms and conditions will also be made available on IAVI’s website.