

This DATA USE AGREEMENT (this “Agreement”) is effective as of

_____ (the “Effective Date”) between

INSTITUTION

acting for and on behalf of its

_____ (“Recipient”) with offices located at

and Vivli, Inc. a Massachusetts nonprofit corporation with an address of #311, 101
Middlesex Tpke, Ste. 6, Burlington, MA 01803-4914 (“Vivli”).

WHEREAS, Vivli manages a research data repository comprised of data contributed by various sponsors of clinical research in an effort to facilitate and encourage research for the public good (the “Data Repository”);

WHEREAS, Recipient is an institution that desires access to certain data and associated information held by Vivli (each a “Data Set” and collectively “Data Sets”);

WHEREAS, Vivli desires to make available to Recipient certain Data Sets to carry out the Research Plan(s) under the terms set forth in this Agreement;

WHEREAS, data from Data Contributor, _____, will be provided to Recipient as part of the Data Set(s); and made available to download via the Vivli platform;

NOW, THEREFORE, Vivli and Recipient agree as follows:

1) Conditions on Use of the Data

- a) Regulatory Approvals; Compliance with Laws. Recipient shall obtain any regulatory or ethical approvals required by law or institutional policy before beginning the Analysis, including but not limited to institutional review board and research ethics committee approval. The parties shall comply with all applicable state/provincial, and local laws, regulations, codes and guidelines, including those regarding the handling, analyzing and reporting of analyses of data.
- b) Data Privacy. Recipient acknowledges the importance of the data privacy of individuals to whom the Data Sets may relate and commits to comply with all applicable national, state/provincial, and local laws and regulations regarding (i) patient/research subject privacy, (ii) the collection, storage, processing, disclosure and use of personally identifiable information, and (iii) other uses and disclosures of the types of data contained in the Data Sets. Recipient shall not share with any third party any username, password, or other account details that Recipient uses to

access any Vivli platform (including the Data Repository) or otherwise provide a third party with access to any Vivli platform (including the Data Repository). Recipient shall employ and maintain reasonable technical and administrative measures to prevent unauthorized or unlawful access or use of any Data Sets or the accidental loss, destruction of, or damage to the Data Sets. In addition, Recipient shall not remove, bypass, circumvent, neutralize or modify any technological protection measures employed by Vivli that are intended to protect the Data Sets.

- c) Re-identification. Recipient agrees not to intentionally attempt to identify any individuals who are subjects of the data contained in any Data Set or others who could be identified from the Data Sets (including but not limited to clinical research staff and relatives of participants). Recipient further agrees not to intentionally combine the Data Sets with other sources of data in a manner that could lead to the identification of any individual.
- d) No Guarantee of Accuracy. Vivli and the Data Contributor(s) provides the Data Set “as is” and make no guarantee that any Data Set is accurate or complete. Recipient shall bear full responsibility and risk as to the accuracy, completeness, usefulness, performance and results derived from any Analysis performed using the Data Sets.
- e) Analysis. Recipient agrees that it will restrict its use of any Data Set to the Analysis described in the Research Plan for which the Data Sets were requested. Recipient may share Data Sets and/or access to Data Sets with third parties who perform services on behalf of, Recipient in its performance of the Research Plan, but only if (i) such third parties are named in the Research Plan, and (ii) Recipient first enters an agreement with such third parties binding the third parties to restrictions on the use of the Data Sets that are no less stringent than those placed on Recipient’s use of the Data Sets herein.
- f) Notification of Covered Person Status. Recipient shall immediately notify Vivli if it or any of its employees, agents, or other parties who receive access to the Data Set hereunder (i) is located in, organized or chartered under the laws of, has its principal place of business in, is ordinarily a resident in, or is 50% or more owned or controlled, directly or indirectly, by entities or persons located in, organized or chartered under the laws of, or having their principal place of business in, a “Country of Concern,” as such term is defined in Section 2(i) below, or (ii) is or otherwise becomes a Covered Person, as that term is defined in Section 2(h) below. Upon receipt of such notification, Vivli may immediately terminate this Agreement if Vivli determines, in its sole discretion, that continuing performance of this Agreement would violate applicable law, including without limitation the U.S. Department of Justice Final Rule entitled “Preventing Access to U.S. Sensitive Personal Data and Government- Related Data by Countries of Concern or Covered Persons,” as codified at 28 CFR 202, and any sub-regulatory guidance issued thereunder (the “DOJ Final Rule”). Vivli shall further have the right to modify the volume of data included in the Data Set if Vivli determines, in its sole discretion, that provision of the Data Set will violate the DOJ Final Rule or other applicable law.
- g) Onward Transfers. Recipient agrees that it shall not engage in any transaction or series of transactions over a twelve (12) month period involving the sale, provision of access to, or similar commercial transaction involving any Data Set(s) that includes the personal health data of more than 10,000 U.S. individuals, the biometric identifiers or human ‘omic data of more than 1,000 U.S. individuals, or the human genomic

data of more than 100 U.S. individuals, regardless of whether such data are anonymized, pseudonymized, de-identified or encrypted, with any Country of Concern or with: (i) a foreign entity that is 50% or more owned, directly or indirectly, individually or in the aggregate, by one or more Countries of Concern or persons described in subsection (ii) hereof, or that is organized or chartered under the laws of, or has its principal place of business in, a Country of Concern; (ii) a foreign entity that is 50% or more owned, directly or indirectly, individually or in the aggregate, by one or more persons described in subsections (i), (iii), (iv) or (v) hereof; (iii) a foreign individual who is an employee or contractor of a Country of Concern or of an entity described in subsections (i), (ii) or (v) hereof; (iv) a foreign individual who is primarily a resident in the territorial jurisdiction of a Country of Concern; or (v) any person, wherever located, determined by the Attorney General to be a Covered Person (each, (i)-(v), a "Covered Person," as that term is used in 28 CFR Part 202).

- h) For purposes of this Agreement, the terms "Country of Concern" or "Countries of Concern" shall mean the People's Republic of China (including Hong Kong and Macau), Cuba, Iran, North Korea, Russia, and Venezuela, including in each case any political subdivision, agency, or instrumentality thereof, and any other country designated as a "Country of Concern" pursuant to the process set forth in 28 CFR Part 202.

2) Publication

- a) Vivli shall make the elements of the Research Plan stated below, publicly available in the Data Repository after the Data Set associated with the Research Plan is made available to Recipient.
- b) Recipient shall provide Vivli with a reference citation upon publication
- c) Recipient further consents that the title of the Research Proposal, name of the Lead Researcher, affiliation, funding source, potential conflicts of interest, summary of the proposed Research , and requested studies (all as provided by the Researcher in the Data Request) will be available on the Vivli platform after the Data Use Agreement is executed, and that the Statistical Analysis Plan (as provided by the Researcher in the Data Request) will be made public by Vivli after the research is published.
- d) Acknowledgment. Recipient agrees to include the following acknowledgment in any publication or presentation of the Analysis Results: "This [publication or presentation, as applicable] is based on research using data from [INSERT DATA CONTRIBUTOR(S) NAME(S)] that has been made available through Vivli, Inc. Vivli has not contributed to or approved, and is not in any way responsible for, the contents of this publication."

3) Term and Termination

- a) Term. The term of this Agreement shall commence on the Effective Date and unless earlier terminated in accordance with the remainder of this Section 3, shall continue in full force and effect for three (3) years from such date (the "Initial Term"). Following the Initial Term, this Agreement shall automatically renew for successive one (1) year periods, unless either party

provides written notice to terminate this Agreement in accordance with the remainder of this Section 3.

- b) Vivli Termination. Vivli may terminate this Agreement entered into hereunder immediately upon the breach by Recipient of any of the terms of this Agreement or use of the Data Sets in violation of applicable law, or in accordance with Section 1 (f) above.

IN WITNESS WHEREOF, the parties hereto execute this Agreement as of the Effective Date.

Vivli, Inc.

Institution Official

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

Read & Acknowledged

Name: _____

Title: _____

Date: _____

Signature Page to Vivli Academic Data Use Agreement



CENTER FOR GLOBAL CLINICAL RESEARCH DATA

VIVLI DATA USE AGREEMENT –
ACADEMIC DATA CONTRIBUTOR

EXHIBIT A

Data Security Addendum to Vivli Data Use Agreement

This Data Security Addendum is attached to, and modifies the terms of, the Data Use Agreement (“the Agreement”) entered into between

[Redacted]

(“Institution”) and Vivli on

[Redacted]

(“Effective Date”), regarding the certain Research Plan(s) attached as Exhibit A therein.

1. By signing this Data Security Addendum, the parties agree to abide by this Data Security Addendum, and further agree that if anything in the Data Use Agreement is inconsistent with those contained herein, the terms of the Data Security Addendum shall govern.

The following additional terms shall be adhered to by the Institution to protect the security of the data provided by Data Contributor:

- a. The data will be stored on a password protected institutional network server (data must not be stored on portable computers, portable storage devices, institutional/personal websites or public clouds).
- b. The network perimeter must be protected by firewall systems to block access from outside the institution.
- c. Where data is required to be on a portable device for a limited period of time – it must be encrypted and deleted from the device when no longer required.
- d. In addition to secure network access, the data will be password protected and only the research team will have access.
- e. The data will be destroyed after the research has been completed. Researchers may retain only encrypted copies of the minimum data necessary at their institution to comply with institutional scientific data retention policy. Notification of data destruction must be sent to the Data Contributor.
- f. Security controls should be on by default; researchers should not have to perform any active action to turn them on.
- g. A data security plan is in place under the accountability of the Chief Information Officer (or equivalent) in which security provisions are set-up before the data are transferred.



- h. Researchers with access to the data are trained on the importance of data security and the security plan.
- i. Data contributors via Vivli are informed of any breach of security or access to data by anyone outside the research team.
- j. Only the following named individuals on the research team shall have access:

2. Institution and Vivli agree that these terms are incorporated into and govern the Data Use Agreement identified above.

IN WITNESS WHEREOF, the parties have executed this Agreement by their duly authorized officers or representatives on the date set forth below, effective as of the Effective Date.

Vivli

By: _____

Name: _____

Title: _____

Date: _____

By:

SIGN HERE

Name:

Title:

Date: