



## INTERNATIONAL SAE CONSORTIUM LTD. DATA USE AGREEMENT

This Data Use Agreement ("Agreement") is made as of the Effective Date (as defined below) by and among International SAE Consortium Ltd., a Delaware USA corporation ("Consortium") and, as applicable, the Investigator or Institution (each as defined below). References to "you" or "I" in this Agreement shall refer to Investigator or Institution, as applicable.

### 1. **Background**

- a. The Consortium is a non-profit corporation formed to carry out scientific research in the public interest. The mission of the Consortium is to identify DNA variants that are clinically useful in understanding and predicting the risk of drug-induced serious adverse events and to make the results of its work publicly available, in a responsible manner, so as to maximize the public benefit. In furtherance of its public mission, the Consortium wishes to make certain genotypic and other data available for use by researchers worldwide to advance the fields of human health and medicine.
- b. Institution has submitted an Application (as defined below) to the Consortium requesting access to the Database and Data for use in the Project (each as defined below). Institution represents that each Investigator identified in the Application (i) is an employee of the Institution and (ii) is an investigator of a scientific research Project described in the Application.
- c. The Consortium has approved the Application and provided this Agreement to Institution and each Investigator. Subject to Institution and each Investigator agreeing to be bound by the terms and conditions of this Agreement, such Investigator will be granted access to the Database and Data for use in the Project solely in accordance with the terms and conditions of this Agreement.
- d. Material changes to the Project described in an Application will require the submission of a new Application. If an Investigator leaves Institution, such Investigator shall have no further right to use or access the Database and/or Data unless and until a new account registration request and Data Use Agreement have been submitted by his/her new Institution and approved by the Consortium. Institution shall notify the Consortium promptly if any Investigator ends his/her affiliation with Institution.

2. **Definitions**. The following terms shall have the meanings set forth below when used in this Agreement.

- *Application* means the account registration request submitted to the Consortium by the Institution which identifies the names of all Investigators, contact information of the Investigators and the Institution, and a description of the proposed Project as to which the Data is intended to be used, including the Project objectives and design and the Data analysis plan.
- *Data* means any and all genetic, phenotypic, association or other data obtained from the Database or Web Site.

- *Data-Derived Publication* means any Publication based, in whole or in part, on any Data or on conclusions drawn from any Data.
- *Data Subject* means an individual person who is the source of any Data or any clinical data or biological sample from which Data has been generated.
- *Database* means the online database in which the Consortium makes Data available to Users.
- *Effective Date* means the date on which the Consortium receives electronic confirmation that the Institution has accepted the terms of this Agreement.
- *Institution* means the research institution submitting the Application identifying the Investigators to which this Agreement shall apply.
- *Investigator(s)* means the principal investigators named in the Application who desire access to the Database in connection with the Project.
- *Project* means a medical, pharmaceutical or biological research project described in an Application.
- *Publications* means, without limitation, articles and abstracts published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research.
- *User* means an individual researcher (including Investigator(s)) participating in a Project who is enrolled at, affiliated with or employed by Institution, and only during the term of such person's enrollment, affiliation or employment.
- *Web Site* means the Internet Web Site through which the Consortium makes access to the Database available to Users.

3. **Conditions on Data Access and Use**. As a condition to use and access the Data, Institution and each Investigator, as applicable, agrees to comply with each of the following requirements, and the Institution shall cause each User to comply with each of the following requirements:

- a. *Use*. Users shall use Data solely in connection with the Project(s) approved in the accompanying Application. Users shall not make clinical treatment decisions based on the Data, as it is intended solely as a research resource.
- b. *Supplemental Restrictions*. Users shall comply with any supplemental data use restrictions identified on the Web Site and corresponding to particular Data files, including, without limitation, restrictions imposed based on patient consents or institutional review board (IRB) or privacy board requirements of organizations supplying biological samples and/or data that underlies the Data.
- c. *Data Subjects*. Users shall preserve, at all times, the confidentiality of information and Data pertaining to Data Subjects. Users shall not use or attempt to use the Data, alone or in concert with other information, to compromise or otherwise infringe the confidentiality of information on Data Subjects and their right to privacy, or to identify or contact any individual Data Subject or group of Data Subjects, to extract or extrapolate any identifying information about a Data Subject from the Data, or to establish a particular Data Subject's membership in a particular group of persons.
- d. *No Transfers*. Users shall not transfer or disclose the Data, in whole or part, or any identifiable material derived from the Data, to others, except as necessary for data/safety monitoring or program management. If a User wishes to share Data with a collaborator who is not a student or researcher at Institution, such collaborator, and his or her Institution, must make a separate application for access to the Data. No User shall sell or distribute all or any part of the Data in any electronic or tangible form, nor grant access to the Data to any third party.
- e. *Reissuance; Destruction of Data*. Upon the request of the Consortium, which shall be made only in order to correct errors, to comply with requests of Data Subjects or to comply with

applicable legal requirements, Users shall destroy earlier versions of Data that have been removed from or reissued or updated in the Database.

- f. *Reproduction.* No User shall reproduce the Data in any electronic or tangible form, except as reasonably necessary to carry out the Project. No User shall take any copy of the Data to any other institution following his/her departure from Institution unless expressly authorized in writing by the Consortium after such new institution has (i) submitted an account registration request to the Consortium and (ii) entered into a Data Use Agreement with the Consortium.
- g. *Publications.*
  - i. All Data-Derived Publications shall acknowledge the Consortium and its sponsors in the manner specified on the "Acknowledgements" page of the Web Site corresponding to the relevant Data.
  - ii. No User may release, publicly present, publish or submit for publication or presentation any Data-Derived Publication prior to the "Publication Release Date" specified on the page of the Web Site corresponding to the relevant Data or as otherwise specified in writing (including via electronic mail) by the Consortium.
- h. *Security.* Institution shall take all reasonable steps to ensure that no unauthorized persons have access to the Data or Database, and to ensure that no Users shall take any action which would be in violation of this Agreement. Such steps shall include, but shall not be limited to, imposing password restrictions on use of the Data and Database, securing Institution's system, and administering and monitoring use of the Data and Database, and the other security measures as may be published by the Consortium from time to time on the Web Site. Under no circumstances shall any User attempt to access or use the Database or Web Site in any manner contrary to the instructions of the Consortium, or in any manner that would be likely to compromise the security or integrity of the Web Site, Database or Data. No User shall attempt to download, upload, use or insert any software, virus, worm, Trojan horse or other code intended to disrupt, corrupt, damage, reproduce, interfere with or provide unauthorized access to the Web Site or Database.
- i. *Compliance.* All uses of Data shall be in compliance with all applicable federal, state, local and foreign laws, rules, regulations and orders including, without limitation, the U.S. Health Insurance Portability and Accountability Act (HIPAA) and the regulations thereunder and the UK Data Protection Act 1998.
- j. *No Modification.* Users shall not modify, falsify or distort the Data for any reason, nor base any Publication on Data that has been modified, falsified or distorted.
- k. *Notification of Breaches.* Within 24 hours of becoming aware of any actual or suspected violation of this Agreement by any User and any breach of Institution's data security measures that could result in the unauthorized use or disclosure of any Data, Institution shall report such breach to the Consortium. Such report shall include the date and nature of the event, what was done to address it and what measures will be taken to prevent further occurrences. Institution shall take such further steps as may reasonably be requested by the Consortium to prevent or remedy any such violation. If Institution fails to remedy any such violation to the Consortium's reasonable satisfaction, the Consortium may terminate or suspend Institution's access to the Data, Database and/or Web Site.

#### 4. **Intellectual Property** .

- a. *Ownership.* Institution and Investigators acknowledge that the Data, Database and Web Site, and all intellectual property rights therein, are owned by the Consortium and/or its third party licensors, and that, other than the limited license granted hereunder, neither Institution nor any

User shall have or obtain any right with respect to such Data, Database, Web Site and intellectual property.

- b. *License*. Consortium hereby grants Institution a limited, non-exclusive, non-transferable, royalty-free license to permit Users to access and use the Data made available by the Consortium through the Web Site for the sole purpose of carrying out the Project in accordance with and fully compliance with the terms and conditions of this Agreement.
- c. *Inventions Based on Data*. Institution and Investigator(s) agree, and Institution shall cause each User to agree, not to file or support any patent application claiming any DNA marker(s), genotype/haplotype-phenotype association or other attribute disclosed as part of, or derived from, the Data or that would prevent or block access to, or use of, any element of the Data, or conclusions drawn directly from the Data.
- d. *No Limitation of Downstream Protection*. Subject to the foregoing, the Consortium acknowledges that intellectual property protection may be appropriate for inventions and discoveries made by researchers, where such inventions and/or discoveries have been enabled by the Data, but are not directly derived therefrom. Such "downstream" inventions may include novel assays, drug targets, therapeutics and diagnostics developed using DNA markers discovered through analysis of the Data, but whose utility is not solely derived from the associations or other information contained in, or generated directly from, the Data. The Consortium acknowledges that this Agreement does not provide the Consortium with any ownership or control of such downstream intellectual property and, accordingly, Institution and Users are not prohibited hereunder from filing or supporting any patent application claiming such "downstream" inventions.

## 5. **Liability** .

- a. *No Warranty*. The Data, Database and Web Site are made available hereunder "AS IS", "WHERE IS", with all defects. The Consortium disclaims all warranties and conditions, either express or implied, with respect to the Data, Database and Web Site, including all warranties and conditions of merchantability, noninfringement, completeness, accuracy and fitness for a particular purpose, or arising from a course of dealing, usage or trade practice. The Consortium specifically disclaims any warranty that the Data, Database or Web Site will meet Institution's or Users' requirements, will be operational or available at any given time, or will operate in combinations or in a manner selected for use, or that the operation of the Database and Web Site will be uninterrupted or error free. The Consortium will be free, in its sole and absolute discretion, to add or remove Data to or from the Database, and to limit or block access to the Web Site, without notice to Institution or any User.
- b. *Exclusion of Damages*. Institution and Investigators acknowledge that access to the Data is being provided free of charge. Accordingly, Institution and Investigators agree that in no event shall the Consortium or any of its officers, directors, members, affiliates, agents or contractors be liable for any damages resulting from use of or access to the Data, loss of data, lost profits, or for any direct, special, indirect, incidental, punitive, exemplary or consequential damages in any way arising out of or in connection with the Data, Database or Web Site or relating to this Agreement, however caused, even if the Consortium has been made aware of the possibility of such damages.
- c. *No Indemnification*. No party to this agreement shall be required to provide any indemnity hereunder to any other party.

## 6. **Term and Termination** . This Agreement shall remain in effect from the Effective Date until the earlier of (a) the date on which Institution no longer retains any Data or any information derived

from Data in its possession or control, (b) Institution's or any User's breach of any provision of this Agreement, (c) Consortium's written notification to Institution that this Agreement is terminated, (d) all Investigators' discontinuation of their employment with Institution, (e) the conclusion of the Project, or (f) the 2nd anniversary of the Effective Date. Upon any termination of this Agreement, Institution shall ensure that all Data in its possession or control is destroyed or deleted, and shall certify such destruction or deletion to the Consortium in writing.

7. **Survival**. Notwithstanding anything else in this Agreement to the contrary, the parties agree that Sections 3.c, 3.g, 4, 5 and 7-11 shall survive the termination or expiration of this Agreement.

8. **Governing Law**. This agreement shall be construed, interpreted and governed by the laws of the State of Delaware, USA without giving effect to its choice of law rules, and excluding any application of the United Nations Convention on Contracts for the International Sale of Goods.

9. **No Assignment**. Neither this Agreement or the rights granted hereunder shall be assigned or transferred by Institution or any Investigator without the prior written consent of the Consortium, such consent not to be unreasonably withheld, and any attempted transfer without such consent shall be void and have no force or effect. The Consortium may assign this Agreement, in whole or in part, or subcontract the operation of the Web Site and Database to one or more third parties, without notice to Institution or Investigators. For purposes of this Section, a merger, acquisition or change of control of Institution shall be deemed to be an assignment. This Agreement shall inure to the benefit of the parties and their permitted successors and assigns.

10. **Publicity**. The Consortium shall be entitled to refer publicly to Institution as a user of the Data and shall be entitled to publicly disclose information regarding the Project including Project name, Institution name, Investigator names, non-technical summaries of the Project goals and purpose, and links to and descriptions of Publications based on the Data. The Consortium does not endorse any Project or other research conducted at Institution, and no User or Institution shall make any public statement implying any such endorsement.

11. **Severability**. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction.

12. **Notices**. All notices to the Consortium shall be sent to: Mr. Arthur L. Holden, Chairman, International SAE Consortium, Ltd., 8770 West Bryn Mawr Avenue, Suite 1300, Chicago, Illinois 60631