INTERNATIONAL SAE CONSORTIUM LTD.

DATA RELEASE AND INTELLECTUAL PROPERTY POLICY

5 November 2009

1. SAEC Background and Mission. The International SAE Consortium Ltd. (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. Upon publication of Public Data (as defined in Section 3), such data will be made available on a non-discriminatory basis to all qualified researchers as set forth in this Policy. No charges will be assessed for access to or use of Public Data. Further, any rights that may be retained by the Consortium will not be exploited for commercial purposes.

2. Application of Policy. This Policy applies to all members of the Consortium ("Members") and all researchers and other organizations whose work is sponsored, contracted or funded by the Consortium ("Contract Researchers"). The agreement to comply with this Policy is a prerequisite and condition to membership in the Consortium or participation in any Consortium activity, including contracted research and development undertaken on behalf of the Consortium, and for use of any Public Data. Specific provisions of this Policy may be implemented and described in greater detail in agreements between the Consortium and the applicable parties. The application of this Policy will be overseen and monitored by the Scientific Management Committee of the Consortium.

3. Definitions. The following terms shall have the meanings set forth below for purposes of this Policy:

"Analytic Results" means all data and associations generated by the analysis of Genomic Data and/or Clinical Data by or on behalf of the Consortium for the Consortium's Research Program. Analytic Results include genotype, haplotype and allele frequencies, genotype/haplotype-phenotype associations, identification of markers, copy number variation and other genetic variations associated with drug related serious adverse events.

"Ancillary Invention" means any invention created by a Contract Researcher while performing work sponsored, contracted or funded by the Consortium and covering methods, tools or discoveries ancillary to the work directly funded by the Consortium. Ancillary Inventions do not include Analytic Results or the conclusions derived therefrom, but may, unless otherwise specified in any agreement between the Consortium and such Contract Researcher, include reagents, genotyping and other equipment, analytical or statistical methodologies or tools, sample collection, storage, preservation and cataloging methodologies and technologies and software and database designs and technologies.

"Clinical Data" means the clinical data that is provided or made available for the Consortium's Research Program, whether or not associated with a particular Sample, and including, without limitation, sample quantity, biochemical characteristics and collection data, as well as subject identification, family history, phenotype, pathology, demographic data, drug exposure or control status, consent status and other subject data, and may include Individual Data.

"Clinical Source" means any supplier of Samples and/or Clinical Data for the Consortium's Research Program. A Member or Contract Researcher that supplies Samples or Clinical Data shall be considered a Clinical Source solely with respect to those Samples and Clinical Data that it supplies.

"Consortium's Research Program" means research conducted by or on the behalf of the Consortium in support of the Consortium's mission.

"Contract Researcher" has the meaning set forth in paragraph 2 above.

"DACC" means the third party (non-Member) Data Analysis and Coordination Center designated by the Consortium, together with any additional Contract Researchers engaged by the Consortium to perform software, data or statistical analysis activities in conjunction with such Data Analysis and Coordination Center.

"Data Analysis Committee" means the Data Analysis subcommittee of the SMC which, for the avoidance of doubt, may include representatives of Members, Clinical Sources, the DACC and third party Contract Researchers, as determined by the Consortium.

"Genomic Data" means genotypic, sequence, haplotype and other data generated from any Sample by or on behalf of the Consortium or which is otherwise provided or made available for the Consortium's Research Program.

"Individual Data" means individually-identifiable subject data (including, without limitation, name, address, date of birth, social security number and the like) and any connection between individual subjects and phenotype data.

"Member" has the meaning set forth in paragraph 2 above.

"Policy" means this Data Release and Intellectual Property Policy as it may be amended from time to time by a two-thirds majority of the Board of Directors of the Consortium.

"Program Data" means all data generated from Research Program Activities, including but not limited to Clinical Data, Genomic Data and Analytic Results. For purposes of this Policy, all Clinical Data associated with Samples used in the Consortium's Research Program shall constitute Program Data, even if such Clinical Data was collected prior to or without funding from the Consortium.

"Public Data" means Program Data that has been designated by the SMC for controlled public release in accordance with the terms of this Policy. Public Data shall not include any Individual Data.

"Public Researcher" means a bona fide scientific researcher with a legitimate research purpose for accessing and using the Public Data who has entered into a data access agreement with the Consortium in a form approved by the Consortium. For the avoidance of doubt, the for-profit or non-profit status of a researcher or the researcher's employer shall not be a factor in determining Public Researcher status.

"Research Program Activities" means discrete activities, and/or phases of research that are carried out under the Consortium's Research Program.

"Sample" means any biological material provided or made available for the Consortium's Research Program, including, without limitation, DNA, tissue samples and cell lines.

"SMC" shall mean the Scientific Management Committee of the Consortium as it is constituted from time to time.

"Sponsored Invention" means any invention created by third parties while performing work sponsored, contracted or funded by the Consortium (such as rights in DNA markers and genotype/haplotype-phenotype associations, as well as the conclusions derived therefrom) and pertaining to the Consortium's Research Program and mission of the Consortium, but excluding Ancillary Inventions. For the avoidance of doubt, Genomic Data and Analytic Results are considered to be Sponsored Inventions hereunder.

4. Procedures for Data Generation, Access, Usage and Release. The following outlines the anticipated pathways for collecting, generating and analyzing data within and on behalf of the Consortium, as well as commitments of the Consortium, Members and others with respect to such data.

a. *Samples and Clinical Data*. The Consortium intends to fund the collection and aggregation of Samples and related Clinical Data from one or more Clinical Sources. Samples will generally be provided by the Clinical Source to a genotyping vendor designated by the Consortium for use in accordance with paragraph 4.b below. Clinical Data will generally be provided by the Clinical Source to the DACC for use in accordance with paragraph 4.c below. Other Sample and Clinical Data pathways may be determined by the Consortium in compliance with its mission and any applicable agreements with relevant Clinical Sources and Contract Researchers.

b. *Genomic Data Generation.* The Consortium will perform, or cause to be performed by its genotyping or other vendor(s), analyses (including quality control) on the Samples as specified by the SMC. The SMC must "approve" each Genomic Data set that is generated following quality control, either in written or electronic form. Following approval of a Genomic Data set, the Genomic Data will generally be provided to the DACC for use in accordance with paragraph 4.c below, or to other Contract Researchers for further analysis in

accordance with the Consortium's instructions. The Consortium, with prior approval of the Board of Directors, may also provide a copy of such Genomic Data to the Clinical Source that supplied the Samples from which such Genomic Data was derived, for such use(s) as the Board of Directors may approve. Unused portions of Samples, as requested by the supplying Clinical Source, will be destroyed or returned to the supplying Clinical Source in a timely manner.

In some cases, Genomic Data may be offered to the Consortium by a third party for the benefit of the Consortium's research. Such Genomic Data will be subject to the same quality control procedures described above and released to the DACC only upon SMC approval as described above.

c. *Data Analysis*. The Data Analysis Committee, in cooperation with the DACC, will determine suitable strategies for analysis of the Clinical Data and Genomic Data. The DACC will perform such analyses in accordance with such strategies and will report any Analytic Results to the Data Analysis Committee. The Data Analysis Committee will not have direct access to Clinical Data or Genomic Data. The Data Analysis Committee, in consultation with the SMC, will evaluate the Analytic Results and may request additional analyses from the DACC. Data Analysis Committee and SMC members who have access to Analytic Results shall use such Analytic Results solely in connection with the Consortium's Research Program, and not for the individual benefit of any institution or company, whether or not a Member of the Consortium. Each such individual will be bound by confidentiality agreements associated with Consortium membership, and will be prohibited from sharing Analytic Results with any individual who is not (i) a member of the SMC or Data Analysis Committee or (ii) an employee of such committee member's employer and involved in approval or oversight of such institution's or company's participation in the Consortium or the Consortium's Research Program or otherwise as approved by the Consortium.

d. *Publication Preparation.* Following the receipt of Analytic Results, members of the Data Analysis Committee and SMC may, independently and/or in collaboration with relevant Contract Researchers, prepare scientific papers based on such Analytic Results for publication in peer-reviewed scientific journals. Each such paper must be provided to the SMC prior to its first submission to a journal. The SMC shall have a period of 45 days in which to provide any comments and to determine whether all appropriate authors have been credited in such paper, and the author shall comply with the SMC's recommendation as to any additional authors. All such papers shall acknowledge the support of the Consortium.

e. *Protection and Handling of Program Data.* Each recipient of Program Data (whether a member of the SMC or Data Analysis Committee, a Genotyping Vendor or the DACC) shall be responsible for complying with all applicable national, state and local laws, rules, regulations, enactments, directives, orders and standards and relevant institutional policies and requirements, and shall be required to maintain the strict confidentiality of any Individual Data. All persons and organizations having access to Program Data (other than Public Data) shall be required to take reasonable security measures to ensure that such Program Data is not compromised, improperly disclosed or misappropriated. Individual Data shall be protected to the greatest extent practicable. Program Data (including Individual Data) other than Public Data shall be used solely in support of the Consortium's Research Program.

f. *Public Data Release.* In order to promote the public welfare and to enable the broadest beneficial use of the results of the Consortium's Research Program, Public Data will be made available to the public at no charge in the manner described in this Policy. In order to limit the risks to privacy of the data subjects and to comply with any other limitations on the use of such data (e.g., limitations contained in consents obtained from data subjects), specific Program Data will not be classified as Public Data unless and until it has been so designated by the SMC. The following rules shall apply with respect to different types of Public Data:

i. *Genomic Data.* Genomic Data generated by or on behalf of the Consortium will be made publicly available no later than twelve (12) months following approval of the corresponding Genomic Data set by the SMC in accordance with paragraph 4.b above.

ii. *Clinical Data; Samples.* Clinical Data necessary to interpret Genomic Data shall be released concurrently with such Genomic Data, provided that Individual Data shall not be publicly released. The Consortium shall not be required to make Samples available to the public, but information regarding the source of Samples giving rise to Clinical Data and Genomic Data shall be released concurrently with the associated Clinical Data and Genomic Data.

iii. *Analytic Results.* Analytic Results shall be publicly released in publications of results by the SMC and its Contract Researchers. Additional public disclosure of Analytic Results shall not be required.

iv. *Inventions.* To the extent not publicly disclosed pursuant to the release of other Public Data, Sponsored Inventions shall be publicly disclosed by the Consortium promptly after reduction to practice. Such disclosure may be in the form of preventative patent filings as described in Section 5.c below. Contract Researchers shall not be required to publicly disclose Ancillary Inventions.

g. *Restrictions on Public Data Access.* The DACC will make the Public Data available through a controlled-access database to all Public Researchers worldwide who have agreed (and whose institutions have agreed) to comply with certain restrictions determined by the SMC. Such restrictions will include the following: (i) not to share the Public Data with any person who is not employed by a Public Researcher, (ii) not to attempt to identify individual subjects represented by genotype or phenotype data, (iii) not to use the Public Data for other than legitimate pharmaceutical or biological research purposes, (iv) not to submit for publication or presentation, or make any other use or disclosure of, any Public Data or any abstract, article or other information that is based on, includes or uses Public Data for a specified time period not to exceed nine (9) months following the Consortium's initial disclosure of such Public Data (the specific restriction period for such Public Data shall be indicated in the database entry for such Public Data), and (v) such other reasonable restrictions consistent with this Policy as determined by the SMC. Public Researchers shall be required to agree to comply with the foregoing restrictions through a signed agreement or certification and/or a "click-wrap" document that must be accepted prior to accessing online Public Data. Any Public Researcher using Public Data

shall acknowledge the Consortium in any resulting oral or written presentation, disclosure or publication relying on such Public Data.

h. *No Preference for Members*. For the avoidance of doubt, except for the limited access granted to Member employees under paragraph 4.c and 4.d above, Members shall have no preferential or early access to the Program Data, and shall only be permitted to access the Public Data on the same terms and conditions as all Public Researchers.

5. Intellectual Property. It is the goal of the Consortium to maximize the public benefit of research supported by the Consortium and, accordingly, to make freely available DNA markers for susceptibility to drug-induced severe adverse events and related data and analyses. Accordingly, the Consortium has adopted this Policy in order to establish rules and procedures regarding the treatment of intellectual property arising from the Research Program Activities conducted and/or funded by the Consortium.

a. *Existing Patents*. The Consortium may seek to identify patents that are essential to the conduct of the Consortium's Research Program or that pose a risk of blocking the effective use of the results of the Consortium's Research Program. The Consortium may request that the holders of such patents (whether or not Members of the Consortium) either contribute them to the public domain or, failing this, grant the Consortium a non-exclusive, royalty-free license to practice such patents without a right to sub-license. Any such request shall be made in a neutral manner without any explicit or implicit promise of positive or negative consequences from the grant or refusal to grant a license. In certain cases, when a royalty-free license is not available, the Consortium may seek (with the approval of its Board of Directors) a royalty-bearing license on the most favorable terms possible in order to enable the Consortium to carry out the Consortium's Research Program in the most effective manner possible. Any such royalties or other consideration to such a licensor shall be paid by the Consortium from its funds, and not by any Member. The Consortium will not knowingly infringe, nor instruct others to infringe, the valid and enforceable claims of any issued patents. Notwithstanding the foregoing, the Consortium will not warrant to any Member or other third party that its activities do not infringe third party patents or other intellectual property rights.

b. *Consortium-Funded Inventions*. The Consortium shall own all intellectual property rights arising from Genomic Data, Analytic Results and other Sponsored Inventions, provided that if a Contract Researcher is prohibited by applicable law from assigning rights in such Sponsored Invention to the Consortium, such Contract Researcher shall grant to the Consortium an exclusive, perpetual, irrevocable, royalty-free license with respect thereto. In no case shall any Contract Researcher performing work funded by the Consortium file or support any patent application covering any Sponsored Invention without the prior written consent of the Consortium. Contract Researchers may retain rights in Ancillary Inventions, and Ancillary Inventions shall be licensed to the Consortium on a non-exclusive, perpetual, irrevocable, royalty-free basis to the extent necessary to support the Consortium's mission. The inventor may retain the right to conduct academic or other non-commercial research using the results of work performed on behalf of the Consortium.

c. *Contribution of Intellectual Property to the Public Domain; Preventative Patent Filings.* The Consortium intends to release all Public Data as early as possible so as to place it in the public domain and reduce the likelihood that use of the Public Data will be encumbered by patents. In some cases, the Consortium may determine that the most effective way to ensure that Public Data is placed in the public domain with the earliest available priority date is to file a provisional patent application covering all novel discoveries made prior to the filing, and shall include one or more claims directed toward the Program Data (including genetic markers and genotype/haplotype-phenotype associations). Subsequent to this provisional application, the Consortium may file additional utility applications to further validate or expand on its initial utility. At the end of the Research Program Activities with respect to a given indication, patent counsel may file a final utility application, with the intention that such application either be abandoned following publication or converted to a statutory invention registration in the U.S. Contract Researchers who develop intellectual property funded by the Consortium will be required to assist the Consortium in any such filings or other procedures deemed necessary by the Consortium to ensure the contribution of such intellectual property to the public.

d. *Inventions Based on Public Data*. Each person accessing or using Public Data, and his/her institution/organization, must 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 Public Data or that would prevent or block access to, or use of, any element of the Public Data, or conclusions drawn directly from the Public Data.

e. *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 Members and/or Public Researchers, where such inventions and/or discoveries have been enabled by the Public Data and/or the Research Program Activities, 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 Public Data, but whose utility is not solely derived from the associations or other information contained in, or generated directly from, the Public Data. The Consortium acknowledges that this Policy does not provide the Consortium with any ownership or control of such downstream intellectual property and, accordingly, Members are not prohibited hereunder from filing or supporting any patent application claiming such "downstream" inventions.