PARTICIPATION AGREEMENT

AABB DONOR HEMOVIGILANCE PROGRAM

This participation agreement ("Agreement") is entered into between the American Association of Blood Banks, a non-profit organization having its principal place of business at 8101 Glenbrook Road, Bethesda, Maryland, 20814 ("AABB"), serving as the AABB Community Manager, and the blood collection facility executing this Agreement ("Collection Facility") so that Collection Facility can participate in the AABB Donor Hemovigilance Program ("Program") using the Donor HART™ Donor Hemovigilance Analysis & Reporting Tool ("Software"), which collects data on adverse reactions occurring in blood donors.

WHEREAS, the Donor HART™ tool is a web-enabled electronic data collection system designed to facilitate the capture and analysis of data on blood donor adverse reaction information and to provide trending and benchmarking capabilities for participating facilities.

AND, WHEREAS, Knowledge Based Systems, Inc. ("KBSI") owns or has the right to grant licenses to use or access the Software and maintains the Software, which was developed under a Small Business Innovation Research grant ("SBIR") from the United States Army and United States Department of Health and Human Services ("Sponsors") as more fully described in the End User License Agreement ("EULA") contained in the Software.

AND, WHEREAS, AABB shall serve as the Community Manager for the Program and work with KBSI using Data collected by the Software from Collection Facilities.

NOW, THEREFORE, in consideration of the foregoing covenants, obligations, and the terms and conditions set forth in this Agreement and other valuable consideration, the receipt and adequacy of which is hereby acknowledged, AABB and Collection Facility agree as follows:

1. Definitions. For purposes of this Agreement, the following terms shall be defined as set forth below:

1.1 Data means information gathered or generated from use of the Software and includes:

1.1.1 Organization Data, which means information specific to a blood collection organization, its designated End Users, its Collection Facilities and regions including names, locations and any identification numbers/codes.

1.1.2 Donor Data, which means information entered into the Software about a specific donor including age, gender, ethnicity, race, height, and weight. When used in the plural sense, Donor Data refers to the information provided to the Software about all donors.

1.1.3 Donor De-identified Data, which means Data that do not contain any information that could link a specific donor, donation event, or adverse reaction event to an individual. All Raw Data entered in to the Software is de-identified by the End User prior to upload.

1.1.4 Adverse Reaction Data, which means information about donor blood donation reactions.
1.1.5 Donation Event Data, which means information about the donation event, including donation date, donation type, procedure type, and collection kit.

1.1.6 Denominator Data, which refers to data that an organization enters into the system to describe overall activity and qualities of donors and donations (e.g., the total number of donations collected in a given month, or the total number of female donors in a given month). These data are used by the system to calculate rate information. Denominator Data may be derived by the Software from all donation information entered into the Software or entered directly into the system by an organization. Denominator Data includes either unit data or summed data from donors or Donation Event Data elements.

1.2 Data may be gathered and used in furtherance of the Purpose as:

1.2.1 Data Set, which means the combined Data of all End Users.

1.2.2 Raw Data, which means data about blood donors, donations, donor adverse reactions and Collection Facilities entered into the Software by an End User prior to review by KBSI and/or AABB;

1.2.3 Scrubbed Data, which means Raw Data after it has been reviewed and "cleaned" so that data errors have been removed and/or missing fields completed;

1.2.4 Extracted Data, which means a subset of Data or the Data Set to be used for a specific research or analysis purpose; and/or

1.2.5 Organization De-identified Data, which means Extracted Data from which Organization Data has been removed or modified such that a donor, donation or an adverse event cannot be linked to any specific blood collection organization, its designated End Users, its Collection Facilities and regions.

1.2.6 Aggregations and Analysis Results Data, which means information generated from Data or the Data Set by the Software or by performing research and analysis on extracts from Data or the Data Set outside the Software using numerical, statistical, or data mining methods. Aggregations and Analysis Results Data may be created by the End User, KBSI, AABB or other third parties authorized by KBSI or AABB. This information can be:

a. Scientific Research Results Data, which means benchmark data, research findings, cohorts and other correlations identified, discovered or computed by the Software or by analyzing Data or the Data Set; or

b. Technical Research Results Data, which means information about the design, functionality, components, features or performance of the Software; or

c. Organization Research Results Data, which means information generated by the End User using their own Data.

1.3 DHWG means the AABB Donor Hemovigilance Work Group.
1.4 **End Users** means blood collection organizations, their designated Software users, and their Collection Facilities and regions that agree to contribute Adverse Reaction Data into the Software.

1.5 **EULA** means the End User License Agreements that KBSI has entered into with End Users.

1.6 **Purpose** means efforts of the Donor Hemovigilance Program to improve the safety of blood donation and the donation experience of the blood donor.

1.7 **Program or DHV Program** means the AABB Donor Hemovigilance program supported by current or future Sponsors.

1.8 **Sponsors** mean the United States Army and the United States Department of Health and Human Services.


2. **Collection Facility Responsibilities.** Collection Facility shall:

2.1 Actively participate in the Program by consistently reporting Data via the Software, in accordance with the User Guide.

2.2 Pay to AABB within 30 days of invoice the non-refundable administrative fee of $_______ for the annual period June 1 through May 31.

2.3 Comply in all respects with the terms of this Agreement and the User Guide.

2.4 Only issue passwords to persons who have the Collection Facility’s authorization to use the Software.

2.5 Ensure compliance with HIPAA rules, as applicable. Collection Facility understands that the Software is not secured to the extent required by privacy and security laws. Among the data requested from End Users are the donor’s date of birth and the date of the reported incident. Collection Facility acknowledges and accepts any risks associated with or arising out of the use or disclosure of such Data. Collection Facility also agrees that neither it nor its administrators will allow a name, social security number, driver’s license number or other personally identifiable code, number or identifier to be input into the Software that would constitute personally identifiable information or identifiable personal health information. Only a completely de-identified donor identification number may be used in conjunction with a donation event record. Collection Facility agrees to indemnify AABB for any damages AABB may suffer as a result of Collection Facility’s failure to comply with this provision.

3. **AABB Role, Rights and Responsibilities.**

3.1 AABB agrees to provide administrative support for the Software including Collection Facility access (password assignment), training, and first-tier help desk support for Collection Facility; and coordination with KBSI and Sponsors.
3.2 AABB agrees to protect Data subject to the terms and conditions contained in Section 4 below.

3.3 AABB and KBSI reserve the right (but shall have no obligation) to pre-screen, review, flag, filter, modify, refuse or remove any or all Data collected via the Software.

3.4 AABB reserves the right to change the amount of the administrative fees charged to Collection Facility to defray administrative, operational, and training costs. AABB will use best efforts to notify Collection Facility in advance of any such fees to be charged to End Users.

3.5 AABB shall serve as the primary spokesperson for the Program.

3.6 AABB is primarily responsible for managing the DHWG, including convening meetings, setting meeting agendas, creating ad hoc subcommittees, managing future developments and changes to the Program definitions and data points. The DHWG shall serve as subject matter experts to direct Data analysis, report preparation, manuscript preparation, develop and implement priorities for data quality assessment, and monitor outcomes by the Program. (KBSI may also perform Data analysis and report preparation in furtherance of the Purpose and as directed by Sponsors).

4. Confidentiality and Data Protection

4.1 AABB will use commercial best practices to protect Collection Facility’s Data in AABB’s possession. End Users shall have no cross-access to Data submitted by other End Users or by any other entities to which access has been granted.

4.2 Collection Facility agrees to the use of its Data and Aggregations and Analysis Results Data by KBSI and AABB as set forth in the Software EULA.

4.3 AABB may retain Data submitted by Collection Facility during the term of this Agreement. After this Agreement has terminated, AABB and KBSI may delete/destroy or continue to use Collection Facility’s Data and Aggregations and Analysis Results Data only for the Purpose.

4.4 Aggregations and Analysis Results Data shall be owned by Collection Facility and considered Collection Facility’s Proprietary Information. Aggregations and Analysis Results Data may also be used by KBSI as set forth in the Software EULA. Aggregations and Analysis Results Data may not be published or shared with anyone other than AABB or KBSI employees or the DHWG, without prior review and approval of the DHWG, except that AABB may use Donor De-Identified and Organization De-Identified Aggregations and Analysis Results Data as part of its Donor Hemovigilance Annual Report.

4.5 In the event that there is a request for any Donor or Collection Facility Information received by AABB (including subpoena or other government request for legally required disclosure of Donor or Collection Facility Information), AABB will promptly notify KBSI and Collection Facility of such request in order to permit Collection Facility to determine whether or not to challenge such disclosure.

5. Proprietary Rights
5.1 Collection Facility acknowledges and agrees that AABB owns all legal right, title and interest in and to AABB’s trademarks, logos, service marks, and domain names.

Collection Facility may not use any AABB trade names, trademarks, service marks, logos, domain names, or other distinctive brand features without the prior written consent of AABB.

5.2 Collection Facility further acknowledges that reports and material provided by AABB in connection with the Program may contain information that is designated proprietary by AABB and that Collection Facility shall not disclose such information without AABB’s prior written consent.

6. **No Warranty and Limitation of Liability.**

6.1 AABB makes no warranties, expressed or implied, with regard to the Software, whether arising by common law, statute or equity, including without limitation, the warranties of merchantability or fitness for a particular purpose. Any implied warranties are null and void to the extent allowed by law. Collection Facility agrees that AABB shall not be liable for special, indirect or consequential damages, even if it has been advised of the possibility of such damages.

6.2 Collection Facility acknowledges that the Software will be populated in part with Data obtained from other End Users. The accuracy of the submitted Data is the responsibility of each Collection Facility. By using the Software, Collection Facility agrees to assume, and does hereby assume, all risks that may be associated with or arise from the use of inaccurate Data. The Software is a collection and analysis tool; it is not intended to prevent adverse events and does not promise to eliminate any or all adverse events.

6.3 AABB shall not be liable for wrongful disclosure of any Data other than disclosure directly caused by the negligent acts or omissions of AABB, its employees or its agents.

7. **Termination.**

7.1 Any expiration or termination of this Agreement will have no effect upon rights or obligations relative to protection of the Data collected, developed or maintained under this Agreement.

7.2 Collection Facility shall have the right to terminate this Agreement with thirty (30) days prior written notice to: AABB, Center for Data and Special Programs, 8101 Glenbrook Rd., Bethesda, MD 20814.

7.3 AABB may at any time, terminate its legal agreement with Collection Facility if:
   a) Collection Facility has breached any provision of this Agreement (or has acted in a manner that clearly shows that it does not intend to, or is unable to comply with the provisions hereof); or
   b) AABB is required to do so by law; or
   c) KBSI ceases to offer the Services; or
   d) Funding for the Software is discontinued; or
e) AABB’s participation in the Program, in AABB’s sole opinion and discretion, is no longer viable or in the best interests of AABB.

8. **Assignment.** Collection Facility shall not assign this Agreement without the prior written consent of AABB.

9. **Amendment.** The terms of this Agreement may be amended or modified only by mutual written agreement of the undersigned parties (Parties).

10. **Entire Agreement.** This Agreement contains the entire agreement and understanding between the Parties and supersedes all prior and contemporaneous agreements, terms, and conditions, whether written or oral, made by the Parties concerning the subject of this Agreement.

11. **Notices.** Any notices required under this Agreement shall be deemed effective on the third business day following transmission via First Class Mail or recognized national courier to the individuals listed on the signature block below or such other addresses as the Parties subsequently may provide by notice.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be executed in its name and on its behalf by its duly authorized representative.

**PRINT NAME OF COLLECTION FACILITY**

By:________________________________________

Print Name: _______________________________

Print Title: ________________________________

Address: _________________________________

Phone Number: ____________________________

Email: ________________________________

**AMERICAN ASSOCIATION OF BLOOD BANKS**

By:________________________________________

Print Name: Dr. Barbee Whitaker

Title: Director, Department of Research

Address: 8101 Glenbrook Road

Bethesda, MD 20814

Phone Number: +1.301.215.6574

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