

CONNECTVIRGINIA NEWBORN SCREENING DATA EXCHANGE AGREEMENT

This ConnectVirginia Newborn Screening Data Exchange Agreement (“Agreement”) is made as of ____, 201_ (the “Effective Date”) by and between ConnectVirginia, HIE, Inc. (“ConnectVirginia”), a Virginia non-member, Non-stock Corporation and _____, a _____ (“Participant”). (ConnectVirginia and Participant may be referred to herein individually as “Party” and collectively as the “Parties.”)

Recitals

WHEREAS, Participant wishes to electronically exchange data with the Virginia Department of General Services, Division of Consolidated Laboratory Services (“DCLS”) for one or more public health purposes including, but not limited to: (i) lab orders or (ii) reportable lab results;

WHEREAS, the **Code of Virginia § 32.1-65** grants DCLS authority to perform genetic and metabolic testing consistent with, but not necessarily identical to, the uniform condition panel recommended by the U.S. Secretary of Health and Human Services and the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children. This includes the collection of specimen and patient specific health information from participants and the participant’s vendor who submits data on behalf of such organizations (“Reporting Entities”). To facilitate the secure and electronic exchange of this data, DCLS has designated ConnectVirginia as the primary pathway through which newborn screening lab orders and results will be exchanged;

WHEREAS, ConnectVirginia has an established connection with the Virginia Department of Health (VDH) and VDH has an established connection with DCLS to provide a secure pathway for purposes of electronically transmitting Newborn Screening data to DCLS. This pathway will not provide ConnectVirginia or VDH with access to the Data or enable them to store the Data transmitted through ConnectVirginia’s Public Health Reporting Pathway (PHRP);

WHEREAS, the Participant is a Reporting Entity that wishes to establish connectivity to the PHRP to enable submission of Data to DCLs for Newborn Screening Data Exchange purposes;

WHEREAS, ConnectVirginia wishes to provide the PHRP to Participant on the terms and conditions set forth herein;

NOW THEREFORE, for good and valuable consideration, the Parties agree as follows:

1. **Services.** ConnectVirginia will give Participant access to the PHRP in accordance with this Agreement. Participant’s Data will be exchanged through the PHRP and between VDH and DCLS. Neither ConnectVirginia nor VDH will have access to the Data, but instead will securely transport the Data from the Participant to DCLS. ConnectVirginia will not store any data on behalf of Participant, other than temporary storage, incident to the transmission of Data through the PHRP.
2. **Participant Responsibilities.**
 - a. **Onboarding Process.** To use the PHRP to transmit Data to DCLS, Participant will have to:
 - i. Identify which of the acceptable transport methods set forth in the Implementation Guide Participant will use to submit Data to the PHRP for transport to VDH, who will in turn, route the data to DCLS;



- ii. Provide any technology that may need to be deployed or utilized by the Participant to provide the necessary level of interoperability between the Participant's system and the PHRP, including, but not limited to, broadband connectivity, hardware, software, or program interfaces;
- iii. Successfully complete testing of the Selected Transport Method; and
- iv. Execute any documents required by ConnectVirginia and DCLS related to Newborn Screening Data Exchange and successfully pass any DCLS testing related to the content of the Data.

Prior to allowing Participant to use the PHRP for the transmission of Data, ConnectVirginia will have to obtain an affirmation from VDH and DCLS that they are prepared to receive such Data. ConnectVirginia will not transport any Data until it receives such affirmation.

- b. *Submission of Data.* Participant shall only use the PHRP to transport Data to VDH, who in turn will transport the Data to DCLS. It shall not use the Newborn Screening Data Exchange connection to transport any other type of information, data or records. Participant is solely responsible for submitting Data to the PHRP for transport. Such responsibility includes, but is not limited to, determining the timing and content of the Data.
 - c. *Malware Protection.* Participant will ensure that it employs security controls that meet applicable industry or Federal standards so that the Data being transported through the PHRP will not knowingly contain any viruses, worms, unauthorized cookies, trojans, "malware," or other program, routine, subroutine, or data designed to disrupt the proper operation of electronic systems, gather sensitive information, or gain access to computer systems or data without authorization or which, upon the occurrence of a certain event, the passage of time, or the taking of or failure to take any action, will cause an electronic system to be improperly accessed, destroyed, damaged, or otherwise made inoperable.
3. ConnectVirginia PHRP Technical Requirements. ConnectVirginia shall establish the technical requirements and procedures for connectivity of Participant's system to the PHRP consistent with one or more national standards for data exchange. Such technical requirements and procedures will be included in the Implementation Guide, which may be changed from time to time. It is the responsibility of the Participant to review the Implementation Guide on an ongoing basis and to ensure the Participant's continued compliance with those requirements. ConnectVirginia shall receive Data in all of the formats accepted by DCLS. ConnectVirginia will not do any testing, monitoring or verification of the content or format of the Data. Any such testing, monitoring or verification is the responsibility of Participant and DCLS.
 4. ConnectVirginia PHRP Financial Requirements. Unless otherwise expressly provided in Exhibit A to this Agreement, during the Term (as defined below) of this Agreement, the PHRP will be provided without charge.
 5. Disclaimers. EXCEPT AS EXPRESSLY STATED IN THIS SECTION 5, ALL SERVICES ARE PROVIDED ON AN "AS IS" AND "AS AVAILABLE" BASIS. CONNECTVIRGINIA, ITS LICENSORS, AFFILIATES, CONTRACTORS, AGENTS AND EMPLOYEES EXPRESSLY DISCLAIM TO THE MAXIMUM EXTENT PERMITTED BY LAW, ALL WARRANTIES, EXPRESSED OR IMPLIED, ORAL OR WRITTEN, INCLUDING, WITHOUT LIMITATION, (I) ANY WARRANTY THAT THE PHRP OR ANY RELATED MATERIALS ARE ERROR-FREE, ACCURATE OR RELIABLE OR WILL OPERATE WITHOUT INTERRUPTION OR THAT ALL ERRORS WILL BE CORRECTED OR WILL COMPLY WITH ANY LAW, RULE OR REGULATION, (II) ANY AND ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE AND NON-INFRINGEMENT, AND



(III) ANY AND ALL IMPLIED WARRANTIES ARISING FROM STATUTE, COURSE OF DEALING, COURSE OF PERFORMANCE OR USAGE OF TRADE. PARTICIPANT EXPRESSLY ACKNOWLEDGES AND AGREES THAT THE PHRP IS NOT DESIGNED OR INTENDED TO MEET ALL OF ITS NEEDS OR REQUIREMENTS, INCLUDING REPORTING THAT IS REQUIRED UNDER APPLICABLE LAWS. PARTICIPANT ASSUMES ALL RESPONSIBILITY FOR THE SELECTION OF THE SERVICES PROVIDED HEREUNDER TO ACHIEVE ITS INTENDED RESULTS. PARTICIPANT SHALL BE SOLELY RESPONSIBLE FOR ENSURING THE ACCURACY OF ALL DATA AND SHALL BE SOLELY LIABLE FOR ITS USE OF THE PHRP. CONNECTVIRGINIA, ITS LICENSORS, AFFILIATES, CONTRACTORS, AGENTS OR EMPLOYEES SHALL HAVE NO LIABILITY FOR ANY CLAIMS, LOSSES OR DAMAGES ARISING OUT OF OR IN CONNECTION WITH PARTICIPANT'S USE OF PHRP INCLUDING, BUT NOT LIMITED TO, DELETION, CORRECTION, DESTRUCTION, DAMAGE, LOSS OR FAILURE TO STORE ANY DATA.

To the fullest extent permitted by law, ConnectVirginia, its licensors, affiliates, contractors, agents or employees' total liability (including attorneys' fees awarded under this agreement) for any claim by Participant under this Agreement, will be limited to the fees paid by Participant for the prior twelve (12) Months. In no event will ConnectVirginia, its licensors, affiliates, contractors, agents or employees be liable for any indirect, special, incidental, exemplary punitive, treble or consequential damages (including, without limitation, loss of business, revenue, profits, staff time, goodwill, use, data, or other economic advantage), whether based on breach of contract, breach of warranty, tort (including negligence), product liability or otherwise, whether or not previously advised of the possibility of such damages.

This section will survive termination of the agreement.

6. Term and Termination. This Agreement shall commence upon full execution by the Parties and shall continue until otherwise terminated by the Parties as set forth herein. This Agreement may be terminated by either Party upon thirty (30) calendar days' prior written notice to the other Party. In the event either Party breaches this Agreement and fails to cure such breach within ten (10) business days' written notice thereof from the non-breaching Party, the non-breaching Party may terminate this Agreement upon written notice to the breaching Party. If the Participant is the breaching Party, then during the ten (10) business day cure period, ConnectVirginia may suspend the Participant's ability to use the PHRP.
7. Agreement's Compliance with Laws and Regulations. The Participant intends and in good faith believes that this Agreement complies with all federal, State and local laws. If any provision of this Agreement is declared void by a court or arbitrator, or rendered invalid by any law or regulation, and if such provision is necessary to effectuate the purposes of this Agreement, the Participant agrees to attempt to renegotiate in good faith the Agreement to comply with such law(s).
8. Notices. Any notice or other communication required under this Agreement shall be in writing and sent to such address as the Participant shall designate in writing. Notices or communications shall be deemed given: (i) upon delivery, if personally delivered; (ii) upon the date indicated on the return receipt, when sent by the United States Postal Service Certified Mail, return receipt requested; or (iii) if by facsimile telecommunication or other form of electronic transmission, upon receipt when the notice is directed to a facsimile telecommunication number or electronic mail address provided during the onboarding process and the sending facsimile machine or electronic mail address receives confirmation of receipt by the receiving facsimile machine or electronic mail address.



9. Governing Law. This Agreement shall be governed by and construed in accordance with the internal laws of the Commonwealth of Virginia without giving effect to the choice of laws principles thereof and shall be deemed to have been executed, entered into and performed within Virginia. Any action brought pursuant hereto shall be brought in the state or federal courts of the Commonwealth of Virginia. The Parties agree that they will not oppose this jurisdiction.
10. Amendment. This Agreement may be amended by ConnectVirginia from time to time. ConnectVirginia will provide Participant with notice of such amendment at least ninety (90) days prior to the effective date of such amendment. If ConnectVirginia provides Participant with notice of an amendment to this Agreement, Participant shall be required to sign such amendment or terminate participation by providing at least thirty (30) days prior written notice of such termination to ConnectVirginia. Notwithstanding the foregoing, no amendment to this Agreement shall be unilaterally proposed to Participant unless such amendment is proposed to all other Reporting Entities utilizing the PHRP.
11. Assignment. Participant may not assign or transfer this Agreement, or any part thereof, without the prior and specific written consent of ConnectVirginia, which consent shall not be unreasonably withheld. Notwithstanding the foregoing, Participant may assign this Agreement to any of its affiliates without ConnectVirginia's consent. ConnectVirginia may assign this Agreement to any successor operator of ConnectVirginia. This Agreement is binding on the respective successors and permitted assigns of the parties. Any purported assignment without such consent shall be null and void.
12. Waiver. No failure or delay by a Party in exercising its rights under this Agreement will operate as a waiver of such rights, and no waiver of any right will constitute a waiver of any prior, concurrent, or subsequent right.
13. Entire Agreement. This Agreement, together with all exhibits, policies and procedures and the Implementation Guide attached hereto or referenced herein, sets forth the entire and only Agreement between the Parties relative to the subject matter hereof. Any representation, promise, or condition, whether oral or written, not incorporated herein, will not be binding upon the Parties.
14. Severability. In the event that a court of competent jurisdiction holds any Section, or any part or portion of any Section of this Agreement, invalid, void or otherwise unenforceable, each and every remaining Section or part or portion thereof will remain in full force and effect.
15. Relationship of Parties. Nothing contained in this Agreement shall constitute, or be construed to create, a partnership, joint venture, agency or any other relationship other than that of independent contractors to this Agreement.
16. Third-Party Beneficiaries. There exists no right of any person to claim a beneficial interest in this Agreement or any rights occurring by virtue of this Agreement.
17. Force Majeure. Notwithstanding any provisions of this Agreement to the contrary, in the event of a disruption, delay or inability to complete the requirements of this Agreement due in whole or in part to any cause beyond the reasonable control of such Party or its contractors, agents or suppliers, including but not limited to utility or transmission failures, failure of phone or data transmission lines or phone or data transmission equipment, power failure, strikes or other labor disturbances, acts of God, floods, fire, natural or other disasters, sabotage, acts of war or terror or other similar events out of the control of the Party, such Party shall not be considered in breach of this Agreement.



- 18. Counterparts. This Agreement may be executed in any number of counterparts, each of which will be considered an original as against the Party whose signature appears thereon, but all of which taken together will constitute one and the same instrument.
- 19. Authority to Sign. Participant warrants that it has the capacity to enter into and perform the obligations under this Agreement and all activities contemplated in the Agreement, and all other corporate and other actions required to authorize it to enter into and perform this Agreement were properly taken.

Each Party has caused this Agreement to be signed by a duly authorized representative below:

ConnectVirginia

Participant

By: _____

By: _____

Printed Name: _____

Printed Name: _____

Title: _____

Title: _____

Date Signed: _____

Date Signed: _____

Return completed agreement to ConnectVirginia via:

Email: Support@connectvirginia.org

Fax: 804-665-2497

Mail: 4900 Cox Road, Suite 245, Glen Allen, VA 23060

Exhibit A

Additional Terms

Financial Commitments of Participant: [none]