IMMUNIZATION REGISTRY PARTICIPATION AGREEMENT
BETWEEN THE
CABINET FOR HEALTH AND FAMILY SERVICES,
DEPARTMENT FOR PUBLIC HEALTH
AND

_____
(Clinic/ Facility Name)

This Immunization Registry Participation Agreement (the "Agreement") is entered into between the Commonwealth of Kentucky, Cabinet for Health and Family Services, Department for Public Health ("DPH"), and the _____ having its principal place of business at _____ (each a "Party" and collectively the "Parties").
(Clinic/Facility Address)

WHEREAS, DPH is a governmental agency within the Cabinet for Health and Family Services, which is responsible for the development and operation of all programs of the cabinet that provide health services and all programs for assessing the health status of the population for the promotion of health and the prevention of disease, injury, disability, and premature death.

WHEREAS, DPH has established the Immunization Registry (the "Registry") to aid health care providers by sharing patient immunization information for Treatment, Payment, Operations, and to facilitate "meaningful use" of Protected Health Information through the Registry in a manner that complies with all applicable laws and regulations, including without limitation those protective to the privacy and security of health information.

WHEREAS, the Kentucky Immunization Registry is a computer based immunization registry and tracking system implement by DPH.

WHEREAS, DPH places an emphasis on electronic health technology as a means of improving patient care, reducing medical errors and making more efficient use of health care dollars by reducing redundant and duplicative services.

WHEREAS, DPH has and will enter into these Agreements with other Health Care Providers, as defined in HIPAA, referred to in this Agreement as "Participants."

WHEREAS, Participants have a common interest in improving patient care, reducing medical errors and making more efficient use of health care dollars by reducing redundant and duplicative services.

WHEREAS, Participants intend to be meaningful users of electronic health record technology as such terms are defined under the American Recovery and Reinvestment Act of 2009 and regulations that may be promulgated thereunder.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants and agreements set forth below, and other good and valuable consideration, the receipt and legal sufficiency of which are hereby acknowledged, and wishing to be legally bound hereby, the Parties hereto agree as follows:

1. DEFINITIONS

Authorized User means an individual authorized by a Participant under an Immunization Registry Participation Agreement to use the Registry to access or provide Data for a Permitted Use.

Data means patient's immunization records provided to the Registry by a Participant. For purposes of the Agreement, Data means information described in Section 4 herein.

Data Registry means electronically providing or accessing Data through the Registry.

Data Provider means a Participant that submits Data to the Registry for use by a Data Recipient.

Data Recipient means a Participant that uses the Registry to obtain Data.

Effective Date means the latest date of a signature of a person with authority to bind a Party to the Agreement.

DPH means the Commonwealth of Kentucky, Cabinet for Health and Family Services, Department for Public Health or its respective officers, directors, employees, successors and assigns.

DPH's Services mean the information sharing and software described in Section 2 and Section 7 of the Agreement, respectively, provided by DPH.

HIPAA means the Health Insurance Portability and Accountability Act of 1996, Title XII of the American Recovery and Reinvestment Act of 2009 (the "HITECH Act") and the Genetic Information Nondiscrimination Act of 2008 ("GINA"), and the regulations promulgated thereunder at 45 CFR Parts 160 and 164, each as may be amended from time to time.

HIPAA Privacy Rule means the regulations promulgated at 45 CFR Parts 160 and 164, as may be amended from time to time.

HIPAA Security Rule means the regulations promulgated at 45 CFR Parts 160, 162 and 164, as may be amended from time to time.

Participant means a Health Care Provider, Local Health Department or the Kentucky Department for Medicaid Services that has entered into an Immunization Registry Participation Agreement that has not been terminated, including the Participant named as a Party to the Agreement.

Permitted Use means uses include, and are limited to:

(a) By Participants:

(i) To obtain a Participant's patient's vaccination information for Treatment, Payment and/or Operations such that patient authorization is not required under HIPAA; and

(ii) To facilitate the implementation of "meaningful use" criteria as required under the American Recovery and Reinvestment Act of 2009 and its related federal regulations, as permitted by HIPAA; and

(b) By the Department for Public Health:

(i) For Treatment and Payment for individuals and/or Operations such that patient authorization is not required under HIPAA, limited to functions related to case management, care coordination, and quality improvement activities,; and

(ii) For public health investigations, prevention and control of outbreaks;

(iii) For grant application and award support, and immunization coverage data with deidentified data from Data submitted to the Immunization Registry; and

(iv) To facilitate the implementation of "meaningful use" criteria as required under the American Recovery and Reinvestment Act of 2009 and its related federal regulations, as permitted by HIPAA.

Operations shall have the definition assigned to Health Care Operations under HIPAA as limited by 45 CFR §164.506(c)(iv).

Treatment shall have the definition assigned to Treatment by 45 CFR §164.501, which includes preventive services.

Other capitalized terms used in the Agreement but not defined in the Agreement shall have the definitions assigned to such terms under HIPAA.

2. DPH OBLIGATIONS

2.1. Services Provided by DPH.

(a) Registry Operation. DPH will maintain and operate the Registry. DPH has entered into a contract with ENVISION, and may contract with other contractors to maintain and operate the Registry or to provide support services. ENVISION or any other contractor of DPH may contract with other subcontractors to maintain and operate the Registry or to provide support services. DPH will require that its subcontractors comply with the applicable terms and conditions of the Agreement.

(b) Services. DPH shall provide standards-based interfaces using web services to support Data Registry with Participants. DPH shall be responsible for building the interfaces to the Participant on the Registry side and shall collaborate with Participants to develop the interfaces required on the Participants' side.

(c) Access to Registry for Permitted Use. DPH will make the Registry available to Participants for Permitted Uses, including: (i) Data Recipients that may access Data through the Registry; and (ii) Data Providers that provide Data for access by Participants though the Registry. DPH may establish arrangements with other health information registries to allow Participants access to additional Data for a Permitted Use. DPH will require contractually that the users of such other health information registries which are permitted to access Data from Participants will limit access to Permitted Use only and will use its best efforts to enforce such contractual requirements. Any change to a Permitted Use must be documented in an Addendum signed by the Parties.

(d) Registry Availability. DPH will make all reasonable efforts to make the Registry available to Participants 24 hours a day, 7 days a week; however, the Registry availability may be temporarily suspended for maintenance or unscheduled interruptions. DPH will make its best efforts to provide reasonable advance notice of any such suspension or interruptions of the Registry availability and to restore the Registry availability.

2.2. DPH Records; Use of Data.

(a) DPH Records. DPH will maintain records of the date, time and records accessed by a Participant through the Registry as set forth in its Policies and Standards. DPH may also maintain a master patient index, a record locator service and other source data as part of the Registry for the benefit of the Participants. Except as provided above, DPH will not maintain, and will not be responsible for either maintaining records of the content of any Data Registry between Participants or inspecting the content of Data.

(b) DPH Use and Disclosure of Information. DPH will not disclose Data or Data Registry Information to any non-Participant third parties except as: (i) provided by the Agreement; (ii) directed in writing by the originating Participant; or (iii) required by order of any court with appropriate jurisdiction over DPH. DPH may access Data and Data Registry Information only for the operation of the Registry, including collecting Data for a master patient index/record locator service, testing, verifying performance, and providing success measurements of the Registry. DPH may use Data that has been de-identified pursuant to 45 CFR §164.514 to measure the success of the Medicaid Transformation Grant or any other federal grant awarded to the any agency of the Cabinet of Health and Family of the Commonwealth of Kentucky funded by the American Recovery and Reinvestment Act, if the use is compliant with HIPAA.

2.3. Safeguards. DPH shall safeguard the confidentiality of all Data obtained by DPH from Participant in connection with the Agreement, and in accordance with applicable state and federal laws including HIPAA. The Parties have entered into a Business Associate Agreement that is incorporated and made a part of the Agreement, whether attached or not.

2.4. Policies and Standards. DPH will establish policies and standards (respectively, "Policies and Standards") that will govern DPH's and Participant's activity on the Exchange, and these Policies and Standards will be made available. These Policies and Standards will govern DPH and Participant use of the Exchange and the use, submission, transfer, access, privacy and security of Data.

(a) Changes to Policies and Standards. DPH may change or amend the Policies and Standards from time to time at its discretion but not inconsistent with the terms and conditions of the Agreement and will notify the Participant of proposed and final changes and will afford Participant an opportunity to comment on such proposed and final changes. DPH will provide Participants notice of such changes to Policies and Standards by electronic mail. Any changes will be effective thirty (30) days following adoption by DPH unless DPH determines that an earlier effective date is required to address a legal requirement, a concern relating to the privacy or security of Data or an emergency situation. DPH also may postpone the effective date of a change if DPH determines, in its sole discretion, that additional implementation time is required. Except

as set forth in the Agreement, Participant will have no ownership or other property rights in the Policies and Standards or other materials or services provided by DPH.

(b) Security. DPH will adopt Policies and Standards that are reasonable, appropriate and consistent with the Agreement and will operate the Registry in accordance with such Policies and Standards to provide that all Data registries are authorized, and to protect Data from improper access, tampering or unauthorized disclosure. Such Policies and Standards will include administrative procedures, physical security measures, and technical security services that are reasonably necessary to secure the Data. DPH and Participant will comply with the security Policies and Standards established by DPH. DPH will maintain sufficient safeguards and procedures, in compliance with HIPAA, to maintain the security and privacy of Data that is provided or accessed through Data registries through the Registry.

(c) Investigations. DPH will adopt Policies and Standards for the investigation and resolution of privacy and security incidents or other concerns relating to compliance with the Agreement. DPH will notify Participant in writing of any compliance concerns related to Participant's use of the Registry, and Participant will cooperate with DPH in its investigation of any compliance concerns or corrective action. Notwithstanding the Policies and Standards or anything in this Agreement, the Parties' reserve their rights to investigate, handle and resolve personnel and medical staff issues in their sole discretion and to maintain confidentiality of such matters.

3. PARTICIPANT OBLIGATIONS

3.1. Limitation of Section 3. The obligations of this Section 3 apply to Participant when it is receiving Data from the Registry.

3.2. Data Registry. By engaging in Data Registry, Participant agrees that its participation in any Data Registry, and use of the Registry by Participant and its Authorized Users, will comply with the terms of the Agreement and applicable laws and regulations.

3.3. Permitted Use. Participant and its Authorized Users will use the Registry only for a Permitted Use. Participant and its Authorized Users will comply with the Agreement and all applicable laws and regulations governing the privacy and security of Data received through the Registry. Data obtained by Participant through the Registry may become part of Patient's medical record. If Participant includes Data obtained through a Data Registry in Patient's medical record, Participant and Authorized User may use such Data only for those purposes permitted by law. Participant will decide in its discretion whether to use the Registry, and to what extent.

3.4. Authorized Users. Participant will identify and authenticate its Authorized Users, in accordance with the Policies and Standards, who may use the Registry for Permitted Use on behalf of Participant. Authorized Users will include only those individuals who require access to the Registry to facilitate Participant's use of the Data

for a Permitted Use. Participant shall require its individual Authorized Users to comply with the terms and conditions of the Agreement, agree to the conditions of their level of access under a separate User Agreement and comply with applicable laws and regulations.

3.5. System Operations.

(a) Systems Necessary to Participate in Registry. Participant, at its own expense, will provide and maintain the equipment, software, services and testing necessary to use the Registry, except for such software expressly provided by DPH pursuant to Section 6 of the Agreement.

(b) Documentation of Information for Patient Treatment; Record Retention, Storage and Backup. As Participant deems necessary, Participant, at its own expense, will maintain records of Data accessed through the Registry and used by Participant for Treatment. Participant will determine the form for such records, which may include incorporation of Data into patients' medical records electronically, by hard copy or by other form of summary, notation or documentation.

(c) Privacy, Security and Accuracy. Participant will maintain sufficient safeguards and procedures, in compliance with HIPAA, to maintain the security and privacy of Data.

4. DATA PROVIDER OBLIGATIONS

4.1. Limitation of Section 4. The obligations of this Section 4 apply to Participant providing Data to the registry.

4.2. Data Registry and Data Submission. By engaging in Data Registry, Participant agrees that: (a) its participation in any Data Registry will comply with the terms of the Agreement and applicable laws and regulations; and (b) the Data provided by Participant can be related to and identified with source records maintained by Participant. Participant will make Data available for the Registry.

4.3. Permitted Use. Participant and its Authorized Users will use the Registry to provide Data only for a Permitted Use. Participant will and will require its Authorized Users to comply with the Agreement and all applicable laws and regulations governing the privacy and security of Data received through the Registry. Participant and DPH acknowledge that Participant will make Data available for access through the Registry only for a Permitted Use.

4.4. System Operations.

(a) Systems Necessary to Participate in Registry. Participant, at its own expense, will provide and maintain the equipment, software, services and testing necessary to participate in the Registry.

(b) Record Retention, Storage and Backup. Participant, at its own expense, will maintain Data backup and retention to maintain records of Data submitted to the Registry.

(c) Privacy, Security and Accuracy. Participant will maintain sufficient safeguards and procedures, in compliance with HIPAA, to maintain the security and privacy of Data.

Data Provided. Timely and accurate data are the basis of an effective immunization registry. Following execution of this Agreement, participant will submit patient's vaccination information to the registry no later than thirty days after new vaccinations are administered. In addition, participants are encouraged to submit previous vaccination data to the registry at that time, if it has not already been submitted. Failure to provide such data in a timely manner shall subject Participant to termination pursuant to Subsection 10.3(b) of the Agreement. DPH staff will work with participants who have electronic historical immunization data to upload that data into the registry.

5. NOTIFICATION OF PARTICIPANT'S BREACH OR VIOLATION

5.1 If Participant knows of an occurrence, activity or practice that constitutes a material breach or violation of the Agreement, Participant agrees to notify DPH within five (5) business days of determining that such occurrence, activity or practice constitutes a material breach or violation of this Agreement and must take reasonable steps to cure the material breach or end the violation. If the steps are unsuccessful, DPH may terminate the Agreement.

6. SOFTWARE LICENSE

6.1. License. DPH grants to Participant for the term of the Agreement a royalty-free, non-exclusive, nontransferable, non-assignable, non-sub-licensable, and limited right to use any software identified by DPH in its technical operation Standards for the sole purpose of participating in the Registry under the terms and conditions of the Agreement. THE SOFTWARE SHALL NOT BE USED FOR ANY OTHER PURPOSE WHATSOEVER, AND SHALL NOT OTHERWISE BE COPIED OR INCORPORATED INTO ANY OTHER COMPUTER PROGRAM, HARDWARE, FIRMWARE, OR PRODUCT. THE SOFTWARE IS LICENSED "AS IS" AND DPH DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES OF ANY KIND, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR TITLE. Participant acknowledges that the software may have been licensed to DPH by third parties, and that the license granted under the Agreement is subject to the extent permitted by law to DPH's grant of license from such third parties. As additional software is developed by or for DPH for the Registry, it shall become subject to the Agreement and a part of this license upon written notice to Participant. This Section 6 applies only to software that is installed on hardware owned or leased by Participant or otherwise provided to Participant by DPH to use the Registry.

7. PROPRIETARY PROVISIONS

During the term of the Agreement, each Party may have access to information about the other Party that: (a) relates to past, present or future business activities, practices, protocols, products, services, information, content, and technical knowledge; and (b) has been identified as confidential ("Proprietary Information") by such Party. For the purpose of this Section, Proprietary Information will not include Data.

7.1. Non-disclosure. The Parties will hold Proprietary Information in strict confidence; (a) not make the Proprietary Information available for any purpose other than as specified in the Agreement; and (b) take reasonable steps to ensure that the Proprietary Information is not disclosed or distributed by employees, agents or consultants (who will have access to the same only on a "need to know" basis) to third parties in violation of the Agreement.

7.2. Damages. In no event shall DPH and their respective officers, directors, employees, successors and assigns be responsible for any indirect, special, incidental, consequential or similar damages to Participant or any other person or entity resulting from Participant's use of the Registry.

8. TERM AND TERMINATION

8.1. Term. The Agreement shall become effective on the Effective Date and shall continue until terminated by a Party as allowed by this Section of the Agreement.

8.2. Termination. The Agreement shall continue in effect and be automatically renewed annually until terminated with or without cause by written notice by a Party.

8.3. Notice. Any notice required under this Section 8 of the Agreement shall be given in accordance with Section 13.9 of the Agreement and Section 3.0 and 4.0 of the Business Associate Agreement attached hereto as Exhibit C and incorporated by reference.

9. WARRANTIES

9.1 No Warranties – DPH. DPH will use its best efforts to correctly transmit Data registries between Participants on a timely basis. DPH MAKES NO REPRESENTATION OR WARRANTY THAT THE DATA DELIVERED TO THE DATA RECIPIENT WILL BE CORRECT OR COMPLETE. DPH MAKES NO WARRANTY OR REPRESENTATION REGARDING THE ACCURACY OR RELIABILITY OF ANY INFORMATION TECHONOLOGY SYSTEM USED FOR THE REGISTRY. **DPH DISCLAIMS ALL WARRANTIES REGARDING ANY PRODUCT, SERVICES, OR RESOURCES PROVIDED BY IT, OR DATA REGISTRYS TRANSMITTED, PURSUANT TO THE AGREEMENT INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE.**

9.2 No Warranties - Participant. Participant expressly disclaims any and all warranties regarding the patient data of Participant through the Registry, including, without limitation, any and all warranties of accuracy, completeness, fitness for a particular use and any other express or implied warranties. Participant acknowledges and agrees that any data accessed by Participant or its Authorized Users is provided on an "as-is" and "where-is" basis, and DPH, its contractors, subcontractors and Participant shall take all reasonable efforts necessary to inform Authorized Users of their responsibility to review, update and confirm the accuracy of any information accessed through the Registry. Use of the Registry is not a substitute for a health care provider's standard practice or professional judgment. Any decision with respect to the appropriateness of diagnoses or treatments or the validity or reliability of information is the sole responsibility of the patient's health care provider. Nothing in this subsection 9.2 is intended to limit Participant's obligations under Section 3 or Section 4 of the Agreement.

10. LIMITATION OF LIABILITY

10.1. Limitation of Liability. Except as provided in Section 6.0 of the Business Associate Agreement, neither DPH nor Participant will be liable to the other for lost profits or lost Data, or any special, incidental, exemplary, indirect, consequential or punitive damages (including loss of use or lost profits) arising from any delay, omission or error in a Data Registry or receipt of Data, or arising out of or in connection with the Agreement, whether such liability arises from any claim based upon contract, warrant, tort (including negligence), product liability or otherwise, and whether or not either party has been advised of the possibility of such loss or damage.

10.2. Not a Medical Service. The Registry does not make clinical, medical or other decisions and is not a substitute for professional medical judgment applied by Participant or its Authorized Users. Participant and its Authorized Users are solely responsible for confirming the accuracy of all Data.

11. HIPAA COMPLIANCE

The Parties agree to comply with, and to cause their respective employees, subcontractors and agents to comply with, as appropriate, HIPAA, as well as other state and federal laws and regulations relating to the security, protection and privacy of individually identifiable health care information. DPH shall in good faith execute any and all agreements that Participant is required to have DPH execute in order that Participant may comply with HIPAA. In the event that either Party or its employees or agents fail to comply with this provision, the complying Party may immediately terminate the Agreement, in addition to seeking other remedies available to it at law or equity.

12. MISCELLANEOUS

12.1. Interpretation. Any ambiguity in the Agreement shall be resolved in favor of a meaning that permits the Parties to comply with HIPAA. Any inconsistency between

the Agreement and the Business Associate Agreement shall be resolved in favor of the Business Associate Agreement.

12.2. No "Designated Record Set". The Parties hereto agree that the Data submitted to the Registry under the Agreement is not a "Designated Record Set" for purposes of individuals' rights to access, inspect or amend "protected health information" about them under the HIPAA Privacy Rules.

12.3. No Third Party Beneficiaries. Nothing expressed or implied in the Agreement is intended to confer, nor shall anything herein confer, upon any person other than the Parties, their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.

13. GENERAL PROVISIONS

13.1. Integration. Except as otherwise specifically stated herein, the Agreement sets forth the entire and only Agreement between DPH and the Participant relative to the Registry. Any representations, promise, or condition, whether oral or written, not incorporated herein shall not be binding upon either Party.

13.2. Incorporation by Reference. All exhibits attached to the Agreement are incorporated by reference and made a part of the Agreement as if those exhibits were set forth in the text of the Agreement.

13.3. Relationship of Parties. Nothing contained in the Agreement shall constitute, or be construed to create, a partnership, joint venture, agency or any other relationship between the Parties other than that of independent contractors to the Agreement.

13.4. Assignment. In no event shall any party assign any of its rights, powers, duties, or obligations under the Agreement without receipt of the prior written consent of the other party, and any attempt to do so shall be void.

13.5. Severability. If any term, covenant, condition or provision hereof is illegal, or the application thereof to any person or in any circumstances shall, to any extent, be invalid or unenforceable, the remainder of the Agreement, or the application of such term, covenant, condition or provision to persons or in circumstances other than those with respect to which it is held invalid or unenforceable, shall not be affected thereby, and each term, covenant, condition and provision of the Agreement shall be valid and enforceable to the fullest extent of permitted by law.

13.6. Governing Law. The Agreement shall be construed and enforced in accordance with, and governed by, the laws of the Commonwealth of Kentucky.

13.7. Enforceability. The Agreement shall be enforceable only by the Parties hereto and their successors pursuant to an assignment which is not prohibited under the

terms of the Agreement. In all other respects, the Agreement is not intended, nor shall it be construed, to create any other third party beneficiary rights.

13.8. Construction. If any language is stricken or deleted from the Agreement, such language shall be deemed never to have appeared herein and no other connotation shall be drawn therefrom. The paragraph headings used herein are for convenience only and shall not be used in the construction or interpretation of the Agreement.

13.9. Notice. Any notice, offer, demand or communication required or permitted to be given under any provision of the Agreement shall be deemed to have been sufficiently given or served for all purposed if delivered personally to the party to whom the same is directed, or if sent by first class mail, postage and charges prepaid, addressed to the address of the Party set forth below.

To DPH:

Governor's Office of Electronic Health Information
Cabinet for Health and Family Services
275 East Main Street, 4W-A
Frankfort, Kentucky 40621
Attention: KHIE Administrator
Phone: (502) 564-7042
Fax: (502) 564-2608
Email address:

With a copy (which shall not constitute notice) to:

Office of Legal Services
Cabinet for Health and Family Services
275 East Main Street, 5W-B
Frankfort, Kentucky 40621
Attention: Privacy Officer
Phone: (502) 564-7905
Fax: (502) 564-7573
Email address
With a copy (which shall not constitute notice) to:

Office of Administrative & Technology Services
Cabinet for Health and Family Services
275 East Main Street, 4W-E
Frankfort, Kentucky 40621
Attention: Security Officer
Phone: (502) 564-6478
Fax: (502) 564-0203

To Participant:

_____
_____
_____
Phone: _____
Fax: _____
Email address: _____

Except as otherwise expressly provided in the Agreement, any such notice shall be deemed to be given on the date ten (10) business days after the date on which the same is deposited in a regularly maintained receptacle for the deposit of United States mail, addressed as provided in the immediately preceding sentence. Either Party may change its address for purposes of the Agreement by giving the other Party notice thereof in the manner hereinbefore provided for the giving of notice.

13.10. Amendments. The Agreement cannot be changed, modified or discharged orally, but only with the written agreement of the Parties hereto.

13.11. Signing Authority. Each person signing the Agreement hereby represents that he or she is authorized to enter into the Agreement on behalf of the Party for which he or she is signing.

IN WITNESS WHEREOF, the parties have executed the Agreement this _____ day of _____, 2020.

DPH	PARTICIPANT
Name: Sarah Wilde	Name: _____
Title: KYIR Manager	Title: _____
Signature: [signature]	Signature: _____
Date: 1/22/2020	Date: _____

BUSINESS ASSOCIATE AGREEMENT BETWEEN
CABINET FOR HEALTH AND FAMILY SERVICES,
DEPARTMENT FOR PUBLIC HEALTH

And

_____
(Clinic/Facility Name)

This Business Associate Agreement ("Agreement") is made by and between _____ ("Covered Entity") and Commonwealth of Kentucky, Cabinet for Health and Family Services, Department for Public Health ("DPH") ("Business Associate"), as of _____, 2020.

RECITALS

WHEREAS, the parties have entered into an Immunization Registry Participation Agreement ("Participation Agreement"), dated _____ ____, 2020, whereby Business Associate provides services to Covered Entity and Business Associate receives, has access to, or creates protected health information in order to provide those services; and

WHEREAS, Covered Entity and Business Associate intend to protect the privacy and provide for the security of protected health information disclosed to Business Associate in compliance with the Health Insurance Portability and Accountability Act of 1996, ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act, (the "HITECH Act"), and regulations promulgated thereunder, and as may be amended from time to time (collectively the "Privacy and Security Regulations"), and other applicable laws; and

WHEREAS, in accordance with the Privacy and Security Regulations, Covered Entity and Business Associate are required to enter into a contract containing specific requirements as set forth in, but not limited to, the Privacy and Security Regulation;

NOW, THEREFORE, in consideration of the foregoing, and for other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, the parties agree as follows:

1.0. Definitions

1.1. "Breach" means the unauthorized acquisition, access, use, or disclosure of protected health information in a manner not permitted by the Privacy and Security Regulations, which compromises the security and privacy of protected health information, as more specifically defined in 45 C.F.R. 164.402.

1.2. "Disclose" and "Disclosure" mean, with respect to protected health information, the release, transfer, provision of access to, or divulging in any other manner of protected health information outside Business Associate's internal operations.

1.3. "Electronic Protected Health Information" or "Electronic PHI" means protected health information that is transmitted by electronic media (as defined by the Privacy and Security Regulations) or is maintained in electronic media. Electronic PHI may be transmitted and maintained on devices such as cell phones, PDAs, text pagers, and USB static discs.

1.4. "Protected Health Information" or "PHI" means information, including demographic information, that (i) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual; (ii) identifies the individual (or for which there is a reasonable basis for believing that the information can be used to identify the individual); and (iii) is received by Business Associate from or on behalf of Covered Entity, or is created by Business Associate, or is made accessible to Business Associate by Covered Entity. PHI includes, without limitation, Electronic PHI.

1.5. "Secretary" means the Secretary of the U. S. Department of Health and Human Services or his or her designee.

1.6. "Services" means those activities, functions, or services that Business Associate provides for, or on behalf of Covered Entity.

1.7. "Unsecured PHI" means PHI that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through use of a technology or methodology specified in guidance by the Secretary.

1.8. "Use" or "Uses" mean, with respect to PHI, the sharing, employment, application, utilization, examination, or analysis of such PHI within Business Associate's internal operations.

1.9. Terms used, but not otherwise defined in this Agreement shall have the same meaning as those terms in the Privacy and Security Regulations.

2.0. Assurances by Business Associate Regarding PHI. Business Associate warrants that it shall comply with relevant portions of the Privacy and Security Regulations as those regulations apply to business associates. More specifically, and insofar that Business Associate has access to, has been provided with, or will be creating PHI regarding Covered Entity's patients, Business Associate warrants and agrees as follows:

2.1. Permitted Uses and Disclosures of PHI. Business Associate shall Use and Disclose PHI only in the amount minimally necessary to perform the Services for or on behalf of Covered Entity, including permitting the Use and Disclosure of PHI by and to "Participants" for "Permitted Use" (as such terms are defined in the Participation Agreement), provided that such Use or Disclosure would not violate the Privacy and Security Regulations if done by Covered Entity. Further, Business Associate:

2.1.1. shall Disclose PHI to Covered Entity upon request;

2.1.2. may as necessary for the proper management and administration of its business or to carry out its legal responsibilities, Use and Disclose PHI if:

2.1.2.1. the Disclosure is required by law, or

2.1.2.2. Business Associate obtains reasonable assurance from the person to whom the PHI is Disclosed that the PHI will be held confidentially and Used or further Disclosed only as required by law or for the purpose for which it was Disclosed to the person, and the person agrees to notify Business Associate of any instances of which the person is aware in which the confidentiality of the PHI has been breached.

Business Associate shall not Use or Disclose PHI for any other purpose.

2.2. Adequate Safeguards for PHI.

2.2.1. Business Associate shall implement and maintain appropriate safeguards to prevent the Use or Disclosure of PHI in any manner other than permitted by this Agreement.

2.2.2. Business Associate shall implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of Electronic PHI that it creates, receives, maintains, or transmits on behalf of Covered Entity.

2.3. Reserved.

2.4. Availability of Internal Practices, Books and Records to Government Agencies. Business Associate agrees to make its internal practices, books, and records relating to the Use and Disclosure of PHI available to the Secretary for purposes of determining Covered Entity's compliance with the Privacy and Security Regulations. Business Associate shall immediately notify Covered Entity of any requests made by the Secretary and provide Covered Entity with copies of any documents produced in response to such request.

2.5. Access to PHI. If Business Associate maintains PHI in a Designated Record Set, it shall make such PHI available to Covered Entity, or as directed by Covered Entity, to the individual identified as being entitled to access and copy that PHI, within the time frame and in a manner specified by Covered Entity.

2.6. Amendment of PHI. If Business Associate maintains PHI in a Designated Record Set, it shall make such PHI available to Covered Entity for the purpose of

amendment and incorporating such amendments into PHI within the time and in such a manner specified by Covered Entity.

2.7. Accounting of Disclosures. Upon Covered Entity's request, Business Associate shall provide to Covered Entity an accounting of each Disclosure of PHI made by Business Associate or its employees, agents, representatives, or subcontractors.

2.7.1. Business Associate shall implement a process that allows for an accounting to be collected and maintained for any Disclosure of PHI for which Covered Entity is required to maintain. Business Associate shall include in the accounting: (a) the date of the Disclosure; (b) the name, and address if known, of the entity or person who received the PHI; (c) a brief description of the PHI disclosed; and (d) a brief statement of the purpose of the Disclosure. For each Disclosure that requires an accounting under this section, Business Associate shall document the information specified in (a) through (d), above, and shall securely retain this documentation for six (6) years from the date of the Disclosure.

2.7.2. To the extent that Business Associate maintains PHI in an electronic health record, Business Associate shall maintain an accounting of Disclosure for treatment, payment, and health care operations purposes for three (3) years from the date of Disclosure. Notwithstanding anything to the contrary, this requirement shall become effective upon either of the following: (a) on or after January 1, 2014, if Business Associate acquired electronic health record before January 1, 2009; or (b) on or after January 1, 2011 if Business Associate acquired an electronic health record after January 1, 2009, or such later date as determined by the Secretary.

2.8. Reporting Breaches of PHI.

2.8.1. Business Associate shall report to Covered Entity:

2.8.1.1. Each access, acquisition, Use, or Disclosure that is made by Business Associate, its employees, representatives, agents, or subcontractors but is not specifically permitted by this Agreement;

2.8.1.2. Any security incident of which it becomes aware. A security incident means the attempted, or successful unauthorized access, acquisition, Use, Disclosure, modification, or destruction of information, or interference with the system operation of an information system; or

2.8.1.3. A Breach of Unsecured PHI.

2.8.2. Business Associate's Notice to Covered Entity

2.8.2.1. Business Associate shall notify Covered Entity's Privacy Official by telephone call immediately following the first day on which Business Associate knows of such Breach.

2.8.2.2. Business Associate shall provide a full written report to Covered Entity's Privacy Official within five (5) business days of verbal notice. Business Associate shall include the following in the written report:

2.8.2.2.1. detailed information about the Breach, and immediate remedial action to stop the Breach; and

2.8.2.2.2. names and contact information of individuals whose PHI has been, or is reasonably believed to have been subject to the Breach.

3.0. Notice to Covered Entity. Any notice required under this Agreement to be given to Covered Entity shall be made to:

Privacy Official:

Phone:

Address:

4.0. Notice to Business Associate. Any notice required under this Agreement to be given to Business Associate shall be made to:

Governor's Office of Electronic Health Information
Cabinet for Health and Family Services
275 East Main Street, 4W-A
Frankfort, Kentucky 40621
Attention: KHIE Administrator
Phone: (502) 564-7042
Fax: (502) 564-2608
Email address:

With a copy (which shall not constitute notice) to:

Office of Legal Services
Cabinet for Health and Family Services
275 East Main Street, 5W-B
Frankfort, Kentucky 40621
Attention: Privacy Officer
Phone: (502) 564-7905
Fax: (502) 564-7573
Email address

With a copy (which shall not constitute notice) to:

Office of Administrative & Technology Services
Cabinet for Health and Family Services
275 East Main Street, 4W-E
Frankfort, Kentucky 40621
Attention: Security Officer
Phone: (502) 564-6478
Fax: (502) 564-0203

5.0. Mitigation and Cooperation. Business Associate shall mitigate, at Business Associate's sole cost and expense to the extent permitted by law, any harmful effect that is known to it for the Breach, or Use, or Disclosure of PHI in violation of this Agreement, as a result of the acts or omissions of Business Associate and/or its subcontractors, provided that Business Associate shall not be required to indemnify Covered Entity. Business Associate shall cooperate with Covered Entity in the notification of individuals as required and in the manner as set forth in the HITECH Act.

6.0. Remedies in Event of Breach. Business Associate recognizes that irreparable harm will result to Covered Entity in the event of breach by Business Associate of any of the covenants and assurances contained in this Agreement. As such, in the event of a breach, Covered Entity shall be entitled to enjoin and restrain Business Associate from any continued violation of this Agreement. The remedies contained in this section shall be in addition to any action for damages and/or any other remedy Covered Entity may have for breach of any part of this Agreement.

7.0. Breach Pattern or Practice by Covered Entity. If Business Associate knows of an activity or practice of Covered Entity that constitutes a material breach or violation of Covered Entity's obligations under this Agreement, Business Associate must take reasonable steps to cure the breach or end the violation. If the steps are unsuccessful, Business Associate must terminate the Services if feasible, or if termination is not feasible, report the activity to the Secretary. Within five (5) business days of discovery, Business Associate shall provide written notice to Covered Entity of any pattern of activity or practice of Covered Entity that Business Associate believes constitutes a material breach or violation of Covered Entity's obligations under this Agreement, and shall meet with Covered Entity to discuss and attempt to resolve the problem as one of the reasonable steps to cure or end the violation.

8.0. Breach Pattern or Practice by Business Associate. If Covered Entity knows of an activity or practice of Business Associate that constitutes a material breach or violation of Business Associate's obligations under this Agreement, Covered Entity must take reasonable steps to cure the breach or end the violation. If the steps are unsuccessful, Covered Entity must terminate the Business Associate's Services if feasible, or if termination is not feasible, report the activity to the Secretary. Within five (5) business days of discovery Covered Entity shall provide written notice to Business Associate of

any pattern of activity or practice of Business Associate that Covered Entity believes constitutes a material breach or violation of Business Associate's obligations under this Agreement, and shall meet with Business Associate to discuss and attempt to resolve the problem as one of the reasonable steps to cure or end the violation.

9.0. Disposition of PHI upon Termination or Expiration. Upon termination or expiration of this Agreement, Business Associate shall either return or destroy, in Covered Entity's sole discretion and in accordance with any instructions by Covered Entity, all PHI in the possession or control of Business Associate or its agents and subcontractors. However, if either return or destruction of PHI is not feasible, Business Associate may retain PHI provided that Business Associate (a) continues to comply with the provisions of this Agreement for as long as it retains PHI, and (b) limits further Uses and Disclosures of PHI to those purposes that make the return or destruction of PHI infeasible.

10.0. Document Retention. Business Associate shall maintain all documentation required by the Privacy and Security Regulations for a period of six (6) years.

11.0. Conflict. In the event there is a conflict between the language of this Agreement and the Services, the terms and conditions of this Agreement shall control.

12.0. No Third Party Beneficiaries. There are no third party beneficiaries to this Agreement.

13.0. Use of Subcontractors and Agents. Business Associate shall require each of its agents and subcontractors that receive PHI from Business Associate to execute a written agreement obligating the agent or subcontractor to comply with all the terms of this Agreement.

14.0. Term and Termination. The term of this Agreement shall be the same as the term of the underlying services agreement. In addition to and notwithstanding the termination provisions set forth in the underlying services agreement, both this Agreement and the agreement may be terminated by Covered Entity immediately and without penalty upon written notice by Covered Entity to Business Associate if Covered Entity determines, in its sole discretion, that Business Associate has violated any material term of this Agreement. The terms and conditions under this Agreement shall survive the termination of the underlying services agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement effective as of the date stated above.

BUSINESS ASSOCIATE	COVERED ENTITY
Name: Sarah Wible	Name:
Title: KYIR Manager	Title:
Signature:	Signature:
Date: 1-22-2020	Date:

PART II: User Information

Please PRINT clearly or TYPE the names and title of all staff that require access to KYIR.

Clinic KYIR Users:

First Name	MI	Last Name	Title	Vaccinator (Y / N)
First Name	MI	Last Name	Title	Vaccinator (Y / N)
First Name	MI	Last Name	Title	Vaccinator (Y / N)
First Name	MI	Last Name	Title	Vaccinator (Y / N)
First Name	MI	Last Name	Title	Vaccinator (Y / N)
First Name	MI	Last Name	Title	Vaccinator (Y / N)
First Name	MI	Last Name	Title	Vaccinator (Y / N)
First Name	MI	Last Name	Title	Vaccinator (Y / N)
First Name	MI	Last Name	Title	Vaccinator (Y / N)
First Name	MI	Last Name	Title	Vaccinator (Y / N)
First Name	MI	Last Name	Title	Vaccinator (Y / N)
First Name	MI	Last Name	Title	Vaccinator (Y / N)
First Name	MI	Last Name	Title	Vaccinator (Y / N)
First Name	MI	Last Name	Title	Vaccinator (Y / N)
First Name	MI	Last Name	Title	Vaccinator (Y / N)

This record is to be submitted to and kept on file with the Kentucky Department of Health Immunization Registry Program, and must be updated every two years.

Please Mail or Fax Page Numbers: 1, 13, 14, 18, 21, and 22 to:

Kentucky Immunization Registry Program
275 East main Street HS2E-B
Frankfort, KY 40602
Phone: (502) 564-0038
Fax: (502) 564-4760

PROGRAM USE ONLY

Date Received:_____

Type of Facility:

- ☐ Local Health Department
- ☐ School
- ☐ Private Practice (Individual or Group)
- ☐ Other Public Program
- ☐ FQHC / RHC
- ☐ VFC Provider Pin# _____

Approved: _____
Date:_____
(Signature)

Entry Date:_____

Entry By:_____
(Signature)