

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

**AND**  
Lexington-Fayette Urban County Government Family Care Center  
(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 Lexington-Fayette Urban County Government Family Care Center having its principal place of business at 1135 Harry Sykes Way (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.

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.

- (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

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.

## 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 TECHNOLOGY 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.**

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

To Participant:

Family Care Center  
1135 Harry Sykes Way  
Lexington, KY 40504  
Phone: 859-288-4040  
Fax: 859-288-4041  
Email address: jrodes@lexingtonky.gov

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

Name: Sarah Wigle  
Title: Kyle Manager  
Signature: [Signature]  
Date: 03/16/2021

PARTICIPANT

Name: Linda Gorton  
Title: Mayor  
Signature: [Signature]  
Date: 5/17/2021

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:



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.

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

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

BUSINESS ASSOCIATE

Name: Sarah Wible  
Title: Vice Manager  
Signature: [Signature]  
Date: 03/16/2021

COVERED ENTITY

Name: Linda Gorton  
Title: Manager  
Signature: [Signature]  
Date: 5/7/2021

**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