

144 State Street Montpelier, VT 05602 (802) 828-1972 http://gmcboard.vermont.gov **GMCB USE ONLY** DUA #: VDH_ClimateHealth_1

DUA Start Date: 1/1/2019

DUA End Date: 12/31/2019

Data Use Agreement for Release of Non-Public Data Elements from The Vermont Uniform Hospital Discharge Data Set

1. Parties

This agreement is made and entered into by and between the GMCB and Vermont Department of Health, hereinafter referred to as "the Authorized User," for the Project Title¹: Investigation of Potential Associations between Exposure to Fine Particulate Matter (PM_{2.5}) and Emergency Department Visits in Vermont.

2. Definitions

For purposes of this Agreement,

- A. "Agent" means those persons who are agents of the Authorized User, in accordance with the federal common law of agency.
- B. "Agreement" means this data use agreement detailing the Authorized User's commitment to data privacy and security and setting forth restrictions, limitations, and conditions on the use and disclosure of the Data Set.
- C. "Application" means the Authorized User's Application for Access to VUHDDS.
- D. "Authorized User" means the individual or entity being given access by GMCB to VUHDDS pursuant to this Agreement.
- E. "Data Set" means the Vermont Uniform Hospital Discharge Data Set being released to the Authorized User, and all data therein.
- F. "Disclose" means to release, transfer, provide access to, or divulge in any manner information outside of the entity holding the information.
- G. "GMCB" means the Green Mountain Care Board established in Title 18, chapter 220 of the Vermont Statutes Annotated.
- H. "HIPAA" means the Health Insurance Portability and Accountability Act of 1996, including the Standards for the Privacy of Individually Identifiable Health Information at 45 CFR Parts 160 and 164 ("Privacy Rule") and the Security Standards at 45 CFR Parts 160 and 164 ("Security Rule"), as amended by subtitle D of the Health Information Technology for Economic and Clinical Health Act.

¹ The Project Title will be provided by the GMCB based on the Application.

- I. "IUA" means an Individual User Affidavit, a form maintained by the Principal Investigator.
- J. "Principal Investigator" means the individual designated by the Authorized User to be responsible for ensuring compliance with the requirements in this Agreement. The Authorized User may also be the Principal Investigator.
- K. "Research" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- L. "State" means the State of Vermont, including the GMCB.
- M. "Sub-User" means any person or entity (e.g., contractor, subcontractor, grantee, or subgrantee) that is given access to the Data Set by the Authorized User, other than as a member of the Authorized User's workforce.
- N. "VUHDDS" means the Vermont Uniform Hospital Discharge Data Set.

3. Authority and Purpose

Pursuant to 18 V.S.A. §§ 9410, 9456, and 9457, the GMCB administers hospital discharge data within VUHDDS. The Vermont Department of Health (VDH) manages the data set by agreement with the GMCB. VUHDDS also includes hospital discharge data for Vermont residents using hospitals in bordering states, including New Hampshire, New York, and Massachusetts that the GMCB receives under interstate agreements with agencies outside of Vermont. VUHDDS is used by the VDH and the GMCB for utilization analyses in the annually-published Vermont Hospitals Report.

To the extent allowed by HIPAA and 18 V.S.A. § 9457, the GMCB seeks to make some of this data available as a resource for individuals and entities to continuously review health care utilization, expenditures, and performance in Vermont. The purpose of this Agreement is to specify the conditions under which the GMCB will release VUHDDS data, and to ensure that the data is accessed, maintained, used, and disclosed in compliance with all applicable statutory, regulatory, and contractual requirements.

4. Data Referenced by this Agreement

Data within VUHDDS can be broadly categorized into three discharge file types: inpatient, outpatient procedures and treatments and emergency department. The GMCB has discretion to manage data for all three discharge file types, some of which may potentially be individually identifiable, either directly or indirectly.

The tables below identify the types of data that will be disclosed to the Authorized User under this Agreement.

Discharge File Type	Years Available	File Year(s) Requested
□ Inpatient	1997-2016	
□ Outpatient Procedures and Treatments	1997-2016	
Expanded Outpatient Procedures and Treatments	2006-2016	
Emergency Department	2003-2016	2007-2016

5. Responsibilities of the Principal Investigator

The Principal Investigator will act as the steward of the Data Set, including, but not limited to,

- A. ensuring that the GMCB has an IUA on file for each person that will be given access to the Data Set and that each such person understands and observes all the restrictions, limitations, and conditions specified in this Agreement;
- B. ensuring appropriate safeguards are implemented to protect the confidentiality of the Data Set and prevent its unauthorized use or disclosure;
- C. tracking and reporting to the GMCB on the uses and disclosures of the Data Set, including notifying the GMCB of any unauthorized uses or disclosures;
- D. seeking and obtaining the consent of the GMCB before disclosing the Data Set to any person or entity not identified in the Application as a data user; and
- E. providing the GMCB with copies of any materials that contain VUHDDS data from or information derived from the Data Set prior to publication or release.

The Principal Investigator may delegate technical responsibility to other personnel within Authorized User's organization, as identified in Attachment A to this Agreement, for the implementation of appropriate safeguards to protect the confidentiality of the Data Set and to prevent its unauthorized disclosure or use.

6. Restrictions, Limitations, and Conditions of Use and Disclosure

The Authorized User, by and through the Principal Investigator, will ensure compliance with the following restrictions, limitations, and conditions:

- A. The Authorized User may not use, disclose, or otherwise grant access to the Data Set or any derivative data, including statistical tabulations derived from the data,
 - i. in a manner that is contrary to law; or
 - ii. for purposes other than those expressly specified in the Application and permitted by this Agreement, without the express written consent of the GMCB unless required by law.
- B. The Authorized User may not disclose:
 - i. personally identifiable information or the identity of abortion services providers from information contained in the Data Set and may not disclose any direct findings, listings, or other information from the Data Set that could be used to identify individual patients or abortion services providers.
- C. The Authorized User may not use the Data Set to identify individual patients and may not link the Data Set in any manner with other data containing personally identifiable information that may enable identification of individual patients.
- D. Prior to calculating aggregated values based on observations or elements, the Authorized User must censor any cell in a data table with a count of 6 or fewer along with another cell in the same row and another cell in the same column to prevent the identification of the cell with a count or 6 or fewer in a table.
- E. The Authorized User may not decrypt or attempt to decrypt any encrypted data for any purpose or disclose any information that has been encrypted or removed from the Data Set.

F. The Authorized User may not produce, publish, disseminate, or make public any information that could be used to determine or ascertain information about insurers or providers that would be deemed proprietary, such as the amount paid by identified insurers or to identified providers for individual procedure codes. This prohibition on public reporting is not applicable to reporting billed or paid amounts at aggregate service levels, such as service bundles, episodes of care, and other types of service aggregations.

7. Disclosures Required by Law

The Authorized User may not disclose the Data Set on the basis that such disclosure is required by law without notifying the GMCB so that the GMCB has the opportunity to object to the disclosure and seek appropriate relief. If the GMCB objects to the disclosure, the Authorized User shall refrain from disclosing the Data Set until the GMCB has exhausted all alternatives for relief.

8. Safeguards

The Authorized User shall implement appropriate administrative, technical, and physical safeguards to protect the confidentiality of the Data Set and prevent its unauthorized use or disclosure. Such safeguards must comply with HIPAA.

9. Review of Publications

Unless a different time period is specified by the GMCB, the Authorized User must provide the GMCB a review copy of any materials proposed to be published or otherwise disclosed at least fifteen (15) business days prior to publication or disclosure, if the materials contain data from the Data Set or information derived from the Data Set (this includes materials understood by the Authorized User to be consistent with the uses stated in the Application). The GMCB may review the proposed materials and determine whether they comply with all pertinent provisions of this Agreement. When multiple reports of a similar nature will be created from the Data Set, the GMCB may, on request, waive the requirement that any subsequent reports or publications be provided to the GMCB prior to release.

10. Reporting

While this DUA is in effect, the Authorized User must file periodic reports, at times specified by the GMCB, with updated information on:

- A. the status of each individual data user for whom an IUA has been filed;
- B. proposed new users that will require access to the Data Set and who will be filing IUAs prior to gaining access to the Data Set; and
- C. details about data disposition and location, as required by the GMCB.

11. Attribution

The Authorized User must prominently state in written materials, publications, and presentations that the analyses, conclusions, and recommendations drawn from VUHDDS are solely those of the Authorized User or the Principal Investigator and are not necessarily those of the GMCB.

12. Minimum Necessary

The Authorized User will limit, and will ensure that any Sub-User limits, Data Set access to the fewest individuals, data elements, and records necessary to achieve the purposes described in the Application or in a sub-agreement approved by GMCB under section 18 of this Agreement.

13. Notification of Unauthorized Access Uses and Disclosures; Mitigation

- A. The Authorized User must immediately report to the GMCB whenever it (or any of its employees or Agents) becomes aware that the Data Set has been accessed, used, or disclosed in a way that is not permitted by state or federal law or that otherwise violates the terms of this Agreement. The Authorized User must require each Sub-User to immediately report to the Authorized User whenever it becomes aware that the Data Set has been accessed, used, or disclosed in a way that is not permitted by state or federal law or that otherwise violates the terms of this Agreement. The Authorized User must require each sub-User to immediately report to the Authorized User whenever it becomes aware that the Data Set has been accessed, used, or disclosed in a way that is not permitted by state or federal law or that otherwise violates the terms of this Agreement.
- B. The Authorized User must mitigate, to the extent practicable, any harmful effect that is known to it of an impermissible use or disclosure of the Data Set. Mitigation may include providing notices to affected individuals. The Authorized User shall draft and carry out a plan of corrective action to address any incident of impermissible use or disclosure of the Data Set. If requested by the GMCB, the Authorized User shall make its mitigation and corrective action plans available to the GMCB. The Authorized User shall require each Sub-User to agree to these same terms and conditions.

14. Ownership

The Authorized User agrees that it has a license to use VUHDDS pursuant to this Agreement only for the term established herein and does not obtain any right, title, or interest in the Data Set.

The Authorized User must acknowledge GMCB as the data steward and VUHDDS as the source of the data in any public reports, publications, presentations, or other materials generated from the Data Set.

15. Reliance on Representations

The Authorized User represents that it is authorized to bind all individuals who may have access to the Data Set to the terms of this Agreement.

The Authorized User represents that the facts and statements made in the Application are complete and accurate and represent the total uses to which the Data Set will be put. The Authorized User further represents that the Data Set is the minimum amount of data necessary to achieve the purposes described in the Application.

The disclosure of the Data Set to the Authorized User is being made in reliance upon the accuracy of all representations made by the Authorized User, including the representations made by the Authorized User in the Application.

16. Termination of Individual Users' Access; Certificates of Destruction

The Authorized User must notify the GMCB at least fifteen (15) days prior to the date an individual user will no longer need access to the Data Set and follow procedures to ensure that the individual user's access has been terminated by this date.

The Authorized User must file certificates of data destruction with the GMCB for terminated users with data or data tables that were generated using the Data Set and were stored in distributed data systems external to the Authorized User.

17. Disclaimer of Warranties

The GMCB makes no warranty concerning the accuracy of the Data Set or its fitness for any particular purpose.

18. Sub-Agreements

The Authorized User may not assign any of its rights or obligations under this Agreement or disclose the Data Set to a Sub-User without the prior written approval of GMCB. The Authorized User must notify the GMCB at least thirty (30) days prior to disclosing the Data Set to a Sub-User and must provide the GMCB with the following information:

- A. an electronic copy of the agreement between the Authorized User and the Sub-User;
- B. an IUA for each proposed individual data user; and
- C. any other information requested by the GMCB.

The Authorized User must ensure that any Sub-User to whom the Authorized User or Principal Investigator provides the Data Set is bound by a written agreement to the same restrictions and conditions that apply to the Authorized User and Principal Investigator under this Agreement. The written agreement must identify the GMCB as direct and intended third-party beneficiaries with the right to enforce any breach of the agreement upon request.

The Authorized User shall be responsible and liable for any use, publication, or other disclosure or release of the Data Set by any of its Sub-Users.

19. Insurance

Before receiving the Data Set, the Authorized User must provide certificates of insurance to show that the following minimum coverages are in effect: IT Professional Liability or Technology Professional Liability insurance with minimum third-party coverage of \$1,000,000.00 per claim, \$2,000,000.00 aggregate; and first party Breach Notification Coverage of not less than \$2,000,000.00. With respect to the first party Breach Notification Coverage, the Authorized User shall name the State of Vermont and its officers and employees as additional insureds for liability arising out of this Agreement.

20. Defense and Indemnity

The Authorized User shall defend the State and its officers and employees against all third-party claims or suits arising in whole or in part from any act or omission of the Authorized User or of any Agent or Sub-User in connection with their receipt, use, disclosure, or other involvement with the Data Set. The State shall notify the Authorized User in the event of any such claim or suit, and the Authorized User shall immediately retain counsel and otherwise provide a complete defense against the entire claim or suit. The State retains the right to participate at its own expense in the defense of any claim. The State shall have the right to approve all proposed settlements of such claims or suits.

After a final judgment or settlement, the Authorized User may request recoupment of specific defense costs and may file suit requesting recoupment in the Superior Court of the State of Vermont, Civil Division, Washington Unit. The Authorized User shall be entitled to recoup costs only upon a showing that such costs were entirely unrelated to the defense of any claim arising from an act or omission of the Authorized User or of the Authorized User's Agent or Sub-User in connection with their receipt, use, disclosure, or other involvement with the Data Set.

The Authorized User shall indemnify the State and its officers and employees if the State, its officers or employees become legally obligated to pay any damages or losses arising from any act or omission of the Authorized User or of an Agent or Sub-User in connection with their receipt, use, disclosure, or other involvement with the Data Set.

The Authorized User agrees that in no event shall the State be obligated to defend or indemnify the Authorized User or any third party, or otherwise be liable for the expenses or reimbursement, including attorneys' fees, collection costs or other costs of the Authorized User or third party.

21. Antitrust Violations

The Authorized User agrees to not bring suit for alleged antitrust violations on the basis of this DUA.

22. Sovereign Immunity

The State reserves all immunities, defenses, rights or actions arising out of the State's sovereign status or under the Eleventh Amendment to the United States Constitution. No waiver of the State's immunities, defenses, rights or actions shall be implied or otherwise deemed to exist by reason of the State's entry into this Agreement.

23. Bankruptcy

The Authorized User agrees that, upon the filing of any petition in bankruptcy by the Authorized User or the initiation of any bankruptcy proceedings against the Authorized User or reorganization proceedings affecting the Authorized User or the claims of creditors of the Authorized User that the GMCB determines might affect the data, the data in whatever form shall automatically revert to GMCB free of all liens and encumbrances. To the extent allowed by federal law, the Authorized User hereby waives all rights to interpose any objections to the reversion or to aid or support the claims of any third party that are averse to the rights of the GMCB under this provision.

24. Payment

Unless the Authorized User is a Vermont State Agency, the Authorized User shall pay VDH the cost associated with processing the approved data release under this agreement.

25. Term; Survival

This Agreement shall expire at 12:00 a.m. on 12/31/2019 ("Expiration Date"), unless, prior to the Expiration Date, the GMCB approves an extension or the Agreement is terminated. The provisions of this Agreement that by their terms encompass continuing rights or responsibilities shall survive the Agreement's expiration or termination.

If the Authorized User is a Vermont agency, the Expiration Date will be two (2) years from the date the Agreement is executed. A Vermont agency must reapply at least sixty (60) days prior to the Expiration Date to ensure continuous access to data. Failure to submit new DUA applications to the GMCB in a timely and complete manner may result in gaps in access to data while the application is under review.

Authorized Users that are not Vermont agencies shall notify the GMCB at least sixty (60) days prior to the Expiration Date and request an extension. The Authorized User shall file any information required by GMCB pertaining to a request for an extension in a timely and complete manner. The term of any extension is wholly at the discretion of GMCB, which may also deny the request and require the Authorized User to file an application for a new DUA. A DUA may not be extended more than once.

26. Enforcement; Penalties

The following are examples of civil and criminal sanctions that may apply, depending on the types of data included in the Data Set:

- A. 18 V.S.A. § 9410, providing for the assessment of administrative penalties of up to \$1,000 per violation for knowing violations of the statute; up to \$10,000 per violation for willful violations of the statute; and up to \$50,000 per violation for knowing failures to comply with the confidentiality requirements of the statute or confidentiality rules adopted pursuant to the statute through use, sale, or transfer of the data or information for commercial advantage, pecuniary gain, personal gain, or malicious harm.
- B. 33 V.S.A. § 1902a, providing for assessment of an administrative penalty of up to \$1,000 for a first violation and up to \$2,000 for any subsequent violation.

27. Location of Data Set

The Data Set may not be transmitted, stored, or transferred by any means outside the continental United States without the express written permission of the GMCB.

28. Destruction of the Data Set; Certificates of Destruction

The Authorized User must ensure that the Data Set is deleted, destroyed, or otherwise rendered unreadable, as directed by the GMCB, within thirty (30) days of the Expiration Date or the termination of this Agreement, or by the date the Data Set is no longer needed for the purposes described in the Application, whichever comes first. The Principal Investigator shall certify that the Data Set has been deleted, destroyed, or otherwise rendered unreadable by submitting a written certificate of destruction to the GMCB.

29. Amendment

This Agreement may only be modified or amended in writing upon mutual agreement of both parties. The Authorized User shall cooperate with GMCB to amend this Agreement from time to time to the extent necessary for the GMCB to comply with changes to 18 V.S.A. § 9410, HIPAA, or other legal requirements that may apply to the Data Set.

30. Interpretation

Any ambiguity, conflict, or inconsistency in the Agreement shall be resolved to require compliance with 18 V.S.A. § 9410, HIPAA, and other requirements that may apply to VUHDDS.

31. Governing Law, Jurisdiction, and Venue

This Agreement will be governed by the laws of the State of Vermont. Any action or proceeding brought in connection with this Agreement shall be brought and enforced in the Superior Court of the State of Vermont, Civil Division, Washington Unit. The Authorized User irrevocably submits to the jurisdiction of this court for any action or proceeding regarding this Agreement.

32. Counterparts; Execution

This Agreement may be executed in counterparts and the exchange of signature pages to this Agreement (in counterparts or otherwise) by facsimile transmission or other electronic transmission (including in the form of a .PDF file) shall be sufficient to bind the parties to the terms and conditions of this Agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement effective upon the Effective Date set forth above. Each person signing this agreement hereby represents that he or she is authorized by the organization on whose behalf he or she is signing to enter into the Agreement.

Green Mountain Care Board		Authorized User	
Signature:		Signature:	
Name:	Susan Barrett	Name:	Mark Levine
Date:		Date:	
Title:	Executive Director	Title:	Commissioner
		Organization:	Vermont Department of Health

Principal Investigator (if different than Authorized User)				
Signature:				
Name:	David Grass			
Date:				
Title:	Environmental Health Program Manager			
Organization:	Vermont Department of Health			