

Application: Vermont Uniform Hospital Discharge Data Set Non-Public Data Elements



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APPLICATION INSTRUCTIONS

Application Review Process

This application is required of all entities requesting a DUA for Vermont Uniform Hospital Discharge Data Set (VUHDDS) Non-Public Data Elements to support a project focused on a specific research purpose or study.

GMCB staff must deem this application complete before initiating the full review process. **This includes submission of all required and applicable optional attachments as listed in the Application Checklist in this application.** Applicants must include a full list of individuals who will have access to the data set upon the effective date of the DUA with this application. Applicants must file Individual User Affidavits (IUA) signed by the Authorized User (AU) or Principal Investigator (PI) for all data users listed on this application. AUs or PIs must ensure that IUAs are filed with GMCB for future data users prior to their access to the data set or risk forfeiture of the DUA and the data set.

The GMCB chartered the [Data Governance Council](#) (DGC) to oversee the stewardship of GMCB's datasets, including the development and revision of principles and policies to guide decisions on data use and disclosure. The DGC supports the GMCB decision-making process for applications requesting use and disclosure of VUHDDS as addressed in this application form. After an application is deemed complete, GMCB will start the application review process that may include a public discussion of the application by the DGC. The GMCB has the discretion to approve or disapprove applications for a DUA.

The Agency of Administration (AOA) under "Procurement and Contracting Procedures" of Bulletin 3.5 is required to review and approve the DUA after the GMCB has approved the application for a DUA.

Final Steps in the Application Process

If approved by AOA, the GMCB and the applicant jointly enter into a DUA that is signed by the Authorized User, Principal Investigator, and GMCB. Prior to receiving the data set approved under the DUA, all individuals accessing and using the data on behalf of the Authorized User must sign IUAs attesting to understanding the appropriate use and disclosure of the data set and agree to comply with the requirements. If state agencies receive access to VUHDDS including out-of-state data, a SPARCS affidavit must also be completed and approved by the State of New York. Only Vermont state agencies are allowed access to the out-of-state data.

If GMCB declines an application, a written statement identifying the specific basis for denial of the application will be provided to the applicant. The applicant may resubmit or supplement the application to address GMCB's concerns. An adverse decision regarding an application may be appealed to the GMCB.

General Instructions

Applicants must complete all required sections of the application and submit an electronic copy of the completed application, including all attachments, to gmc.data@vermont.gov. Incomplete applications will not be reviewed until the applicant has provided all required information. An

application checklist is provided to help ensure that your application is complete. For questions about the application process, gmcb.data@vermont.gov

Definitions

Agent: Means any individual or entity (e.g., a contractor, subcontractor, grantee, or subgrantee) acting on behalf of the Authorized User and subject to the Authorized User's control or accessing the Data Set on behalf of the Authorized User.

Authorized User: The Authorized User (AU) is typically an organization or agency. The AU signatory to the Application and the DUA must have the authority to sign legally binding agreements on behalf of the organization or institution.

Data Custodian: The data custodian is responsible for the establishment and maintenance of physical and technical safeguards to prevent unauthorized access to and use of the data set. Agencies may designate multiple data custodians for different departments and programs. The principal investigator may also be the data custodian.

Data Redisclosure: Any Vermont state agency or non-state entity with a DUA that intends to redisclose the VUHDDS data set or any custom extracts of the data set to external agents to support projects approved under the DUA must file a Data Redisclosure Request with the GMCB for review and approval prior to the redisclosure. After the GMCB has approved redisclosure of data to an external agent, the GMCB may request its data collection vendor to generate custom data extracts for external agents.

Institutional Review Board (IRB): An institutional review board (IRB), also known as an independent ethics committee (IEC), ethical review board (ERB), or research ethics board (REB), is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans.

Personally Identifiable Information (PII): The term PII refers to information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual. The definition of PII is not anchored to any single category of information or technology. Rather, it requires a case-by-case assessment of the specific risk that an individual can be identified.

Source: <https://www.gsa.gov/reference/gsa-privacy-program/rules-and-policies-protecting-pii-privacy-act>

Principal Investigator (PI): The Principal Investigator means the individual designated by the Authorized User to be responsible for ensuring compliance with all the restrictions, limitations, and conditions of use and disclosure specified in the DUA. The Principal Investigator may delegate technical responsibility to other personnel for the establishment and maintenance of security arrangements to prevent unauthorized access to and use of the data.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

State Entity: Vermont state agencies, contractors, or other external agents performing work for the State of Vermont. A non-state entity is not a Vermont state agency or an agent performing work directed and funded by the State of Vermont.

Application Checklist

(For use by the applicant. Applicants must include all required attachments and applicable optional attachments)

Completed Application

- Section 1:** Research Summary
- Section 2:** Data Management Plan
- Section 3:** Project Team *(Including data users for whom signed IUAs are being filed)*
- Section 4:** Data Transmission and Receipt
- Section 5:** Signatures

Required Attachments

- Attachment 1:** VUHDDS Research File Specification
- Attachment 2:** Entity's Data Governance and Protection Policies and Procedures.

Optional Attachments Applicable to Proposed Redisclosures of the Data or Extracts

- Attachment 3:** Copy of proposed contracts, subcontracts, or any other agreements with external agents requiring redisclosure of the data set or custom extracts.
- Attachment 4:** Data Redisclosure Request must be filed for every external agent identified under Attachment 3 to whom the data or data extracts will be re-disclosed by the entity in possession of the DUA.
- Attachment 5:** Data Governance Policies and Procedures for every external agent identified under Attachment 3 that will be receiving and managing the data set or extracts of the data set.

APPLICATION

Section 1: Research Summary

This section summarizes the specific research purpose of the project requiring access to a limited use health claims research data set during the term of the DUA. The Authorized User must discuss any proposed changes in the research purpose that are not specified in this application with the GMCB. The GMCB may require the filing of an application for proposed changes in data use and the research purpose.

Answer every question in this section. If a question does not apply to your research project, indicate that the item is "Not Applicable." Do not leave a question blank or the application will be deemed incomplete.

Project Overview

Authorized User Signatory Name & Title:	
Organization/Entity Name:	
Type of Organization	<input type="checkbox"/> Federal or State government entity outside of Vermont <input type="checkbox"/> Contractor of Federal or State government entity outside of Vermont <input type="checkbox"/> Academic Institution <input type="checkbox"/> Non-profit research organization <input type="checkbox"/> Participant in the Vermont health care system financing, insurance, or delivery system with direct impacts on the Vermont population <input type="checkbox"/> Participant in health care financing, insurance or delivery systems outside of Vermont <input type="checkbox"/> Health care enterprise such as manufacturers or distributors of pharmaceuticals and medical technology; designers and developers of health systems and facilities, etc. <input type="checkbox"/> Other: Please describe below
Principal Investigator Name & Title (if different from Authorized User):	
Project Name (Specify a topic or study):	

Brief Project Description:
Project Start Date:
Project End Date:
Funding Source(s) <input type="checkbox"/> State <input type="checkbox"/> Federal <input type="checkbox"/> If Other, please describe:
If you intend to redisclose the data to contractors, subcontractors, or other external parties, identify parties:

Authorized User Acknowledgements

Please initial each item indicating your agreement with conditions of use.

() <i>I agree that I have the authority to sign legally binding agreements on behalf of the organization or institution as applicable to this application and the attached Data Use Agreement (DUA).</i>
() <i>I have read and agree to the terms of the attached DUA. I understand the contents of the attached DUA may only be modified or amended in writing upon mutual agreement of both parties.</i>
() <i>I have read and agree to cooperate with the GMCB to amend the DUA 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.</i>
() <i>I understand and agree that I am required to file signed Individual User Affidavits (IUAs) with the GMCB for every individual data user within my organization and those employed by any contractors, subcontractors or organizations outside my organization approved by the GMCB to access and use VUHDDS. I must file the IUAs prior to receipt of the data set and as new users join the project or risk forfeiture of the data set and the DUA.</i>
() <i>I understand and agree that I must obtain the express written approval of the GMCB to release the data set or any derived extracts of the data to any agents or parties outside my organization. I must file a Project Review Form (PRF) with the GMCB for review prior to any re-disclosure of the data set to parties outside of my organization or risk forfeiture of the data, the DUA and be subject to civil and criminal sanctions and penalties for an unauthorized disclosure of data.</i>

Project Questions

Answer the following questions about your research project.

Yes <input type="checkbox"/> No <input type="checkbox"/>	Is the project directed by the State of Vermont including Vermont state agencies and UVM?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Is this project partially or wholly funded by the State of Vermont?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Will products generated from the project be used for a proprietary, commercial purpose to generate revenues and income? <i>If yes, explain below:</i>
Yes <input type="checkbox"/> No <input type="checkbox"/>	Is the project useful for determining the capacity and distribution of existing health care resources?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Is the project useful for identifying health care needs and informing health care policy?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Is the project useful for evaluating the effectiveness of intervention programs on improving patient outcomes?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Is the project useful for comparing costs between various treatment settings and approaches?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Is this project useful for providing information to consumers and purchasers of health care?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Is this project useful for improving the quality and affordability of patient health care and health care coverage?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Does the project directly support public health activities?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Does this project support educational purposes such as exploring the claims data for quality, potential uses, health services research training, or integration with other data sets?
Yes <input type="checkbox"/> No <input type="checkbox"/>	Does this project anticipate re-disclosure of the data set or analytical files generated from the data set to any identifiable external agents under contracts, grants, and agreements for research purposes that have been specified? <i>If yes, you must file a redisclosure request.</i>

Requested Data

Indicate the types of files and file years being requested. Note, only the minimum amount of data needed to complete your study will be approved for release.

Discharge File Type	Years Available	File Year(s) Requested
<input type="checkbox"/> Inpatient	1997-2016	
<input type="checkbox"/> Outpatient Procedures and Treatments	1997-2016	
<input type="checkbox"/> Expanded Outpatient Procedures and Treatments	2006-2016	
<input type="checkbox"/> Emergency Department	2003-2016	

Indicate the non-public data elements that are necessary for your study using **Attachment 1: VUHDDS Research File Specification**. Each checked field must have an associated intended use. If your study can be achieved using a subset of data or data grouped in a particular way, please indicate so. For instance, if you are looking at the pediatric population you may request only those records where the patient is less than 19 years old. In addition, you may prefer to have the patients grouped by a range of ages.

Project Overview

Summarize the purpose and objectives of the proposed research. Describe how the research will contribute to generalizable knowledge that would also be applicable to the Vermont population, health, and health care and, if applicable, to the State of Vermont supporting the development, implementation, and evaluation of programs administered by Vermont state agencies.

Summarize the credentials, skills, and experience of the Principal Investigator and key research staff that are evidence that the Data Set will be used to conduct and support systematic investigations guided by expertise in the subject matter and research methods, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Explain how you will ensure that your organization and external agents performing state-directed research will have access to the minimum necessary data to support specified research purposes and projects.

List and describe any identifiable record-level data files or other record-level data sources you are planning to use in conjunction with the requested VUHDDS data.

Identify and briefly describe the funding source(s) for the proposed research including both internal and external sources that may be in the form of state and federal funding, grants, and other sources. Describe the relationship between the funding source(s) and your organization.

Section 2: Data Management Plan

This section relates to the policies and procedures your organization will use to ensure the proper management of VUHDDS. The GMCB recognizes the applicability of best practices for information security and privacy used in the CMS Data Privacy Safeguard Program (DPSP)¹ to the review of VUHDDS DUA applications. Respond to every question about your organization's and those of approved entities external to your organization policies and procedures to ensure technical and administrative safeguards over the data.

Please answer the questions in each section with references to any attached documents. If questions are not answered completely, the application will be deemed incomplete.

Physical Possession and Storage of Data Files

Include specific references to the Data Governance and Protection policies and procedures documents filed with this application under Attachments 2 and 6 in your responses to the items below. ***Do not simply cite a cross-reference to the policy and procedure documents in lieu of answering each question.***

Describe how your organization will maintain an accurate and timely inventory of VUHDDS including original files received and any derived files used within your organization or released to external agents under state contracts and agreements.

Describe how your organization will ensure and monitor the compliance of all members of research teams both in-house and those employed by approved external agents with privacy and security policies and procedures as described in the documentation filed under Attachments 2 and 6 to this application and as required by the DUA.

Describe the procedures your organization will take to track the status and roles of the research team and notify GMCB of any project staffing changes.

Describe your organization's training programs that are used to educate staff on how to protect sensitive data with personally identifiable information, protected health information, and other sensitive financial, socioeconomic, and personal information.

Describe the protocol that would be followed by your organization or that of approved external agents, if applicable, to report and mitigate a breach in the security of the data set. Who will be responsible for notifying the GMCB of any suspected incidents of a breach in the security of the VUHDDS data?

What actions will your organization and approved external entities take to physically secure the data files? This includes files in motion, or on servers, local workstations, and hard media.

Please explain if your organization intends to transmit, store, or transfer the data set or any derived files outside the continental United States.

¹ "Data Privacy Safeguard Program Information Security and Privacy Best Practices" listed under Additional Resources published on <https://www.resdac.org/resconnect/articles/158>

Data Sharing, Electronic Transmission, Distribution

Include specific references to the Data Governance and Protection policies and procedures documents filed with this application under Attachments 2 and 6 in your responses to the items below. ***Do not simply cite a cross-reference to the policy documents in lieu of answering each question.***

Describe what your organization's policies and procedures will be for sharing, transmitting, and distributing VUHDDS and any derived files.

Describe your organization's methods and those of approved external agents for tracking, monitoring, and auditing access and use of sensitive data such as VUHDDS.

Describe the policies and procedures and procedures your organization and approved external agents use to define data access privileges for individual users of the data, including the Principal Investigator, Data Custodian, analysts and researchers, administrative support, and IT support.

Explain the use of technical safeguards for data access (which may include password protocols, log-on/log-off protocols, session time out protocols, and encryption for data in motion and data at rest).

If approved external agents will have access to the data please describe how that organization's analysts will access the data file, e.g., VPN connection, travel to your organization, or house the data at other locations.

If additional copies of the data will be housed in separate locations, list the locations and describe how the data will be transferred to these locations.

Data Reporting and Publication

Explain your process for reviewing publications prior to dissemination to ensure accurate and appropriate representation of your data sources, analytic methodology, results, caveats, and disclaimers. Describe how your publications will be reviewed to ensure compliance with requirements in the DUA addressing small n suppression, disclaimer of any GMCB endorsement of findings, and data source citation.

Completion of Research Tasks and Data Destruction

Describe how you will complete the Certificate of Data Destruction for the data set and derived files stored by your organization or by approved external agents and how the data will be deleted, destroyed or rendered unreadable by all parties with access to the files upon completion of the project.

Describe your organization’s policies and procedures and those of external agents used to protect VUHDDS data files when individual staff members of research teams terminate their participation in research projects (which may include staff exit interviews, return of passkeys, and immediate access termination for example).

Describe your organization’s policies and procedures to ensure original or derived data files, including non-published aggregate reports, are not used following the completion of the project.

Section 3: Project Team

In this section, list the anticipated individual users within your organization and external agents such as contractors and subcontractors, and project roles. **Signed IUAs for individual users within your organization and those employed by external entities accessing the data must be filed prior to receipt of VUHDDS and on an ongoing basis as project staffing may change.**

Authorized User (Can legally bind the applicant’s organization to agreements)

Please provide contact information for the Authorized User’s signatory.

Name and Title of Signatory for the Authorized User		
Organization Name		
Street Address		
City	State	Zip
Telephone		Email

Principal Investigator

Please provide contact information for the PI if different person than the AU.

Same as Authorized User Signatory

Name and Title of Principal Investigator 1
Organization Name
Street Address

City	State	Zip
Telephone		Email

Data Custodian(s)

Provide contact information for the data custodian for your organization who will store VUHDDS or derived files.

Same as Authorized User Signatory

Name and Title of Data Custodian (State Agency)

Organization

Street Address

City	State	Zip
Telephone		Email

Section 4: Data Transmission and Receipt

The Vermont Department of Health (VDH) is the GMCB's VUHDDS data manager and will provide instructions and requirements for receiving the transmission. VDH may charge a processing fee to non-state entities for the cost associated with processing the approved data release, and the total fee will be determined by VDH. Please identify your primary contact below for setting up the logistics transmission of the approved data extract. The primary contact must either be the Authorized User or Principal Investigator or Data Custodian identified on the DUA or be designated by the AU or PI.

Primary Contact for Planning Data Transmission Logistics

Name:
Title/Role in the Project:
If not AU, PI or DC, designated by:
Email Address:
Phone Number:
Organization/Agency Affiliation:
Street, City, ZIP Address:

Section 5: Signatures

All statements made in this application are true, complete, and correct to the best of my knowledge.

Authorized User Name:

Signature:

Date:

Principal Investigator 1 Name (if different from Authorized User)

Signature:

Date:

Principal Investigator 2 Name:

Signature:

Date:

GMCB Processing Section

For GMCB Use Only

Date Application Deemed Complete:

GMCB Application Approval Date/GMCB Initials:

Date Applicant Notified of Approval:

Application Disapproval Date:

Date Applicant Notified of Disapproval/GMCB Initials

Summary of reasons for disapproval:

Data Use Agreement (DUA) Template

For reference only.

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 _____, hereinafter referred to as “the Authorized User,” for the Project Title²: _____.

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.
- 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.

² The Project Title will be provided by the GMCB based on the Application.

- 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.

Table 1: Files requested

Discharge File Type	Years Available	File Year(s) Requested
<input type="checkbox"/> Inpatient	1997-2016	
<input type="checkbox"/> Outpatient Procedures and Treatments	1997-2016	
<input type="checkbox"/> Expanded Outpatient Procedures and Treatments	2006-2016	
<input type="checkbox"/> Emergency Department	2003-2016	

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 of 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.

- 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 GMCG. 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 adverse 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 _____ (“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:

Name:

Date

Date:

Title:

Title:

Organization:

**Principal Investigator (if different than
Authorized User)**

Signature:

Name:

Date:

Title:

Organization:

FOR REFERENCE ONLY