

VHCURES Data Linkage Request



GREEN MOUNTAIN CARE BOARD

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INSTRUCTIONS

Introduction

The Vermont legislature authorized the collection of eligibility and claims data for Vermont residents to enable the Green Mountain Care Board (GMCB) to carry out its statutory duties that include determining the capacity and distribution of existing resources; identifying health care needs and informing health care policy; evaluating the effectiveness of intervention programs on improving patient outcomes; comparing costs between various treatment settings and approaches; providing information to consumers and purchasers of health care; and improving the quality and affordability of patient health care and health care coverage. (18 V.S.A. § 9410) The GMCB can make the VHCURES data set available to the extent permitted by the Health Information Portability and Accountability Act (HIPAA) and other pertinent state and federal laws and regulations.

The claims and eligibility data available under a data use agreement can be broadly grouped into three lines of business including commercial, Medicaid, and Medicare. The GMCB has independent discretion to make decisions regarding the use and disclosure of commercial insurer data. The Department of Vermont Health Access (DVHA) and the GMCB share discretion with respect to the Medicaid data subset. DVHA must approve the use and disclosure of Medicaid data and must sign the Data Use Agreement (DUA) for authorized users of the Medicaid data subset. Per an agreement with the federal Centers for Medicare and Medicaid Services (CMS), the Medicare data subset is available only to Vermont State Agencies and entities performing research that is directed and partially funded by the State of Vermont. CMS has granted GMCB independent discretion to make decisions regarding the use and disclosure of the Medicare data subset by Vermont state agencies.

The GMCB must approve all requests from state agencies and other organizations to link the VHCURES data with other identifiable data sources or any other data sources that could be used to reidentify individuals in the VHCURES data set.

Data Governance Council

The GMCB chartered the [Data Governance Council](#) (DGC) to oversee the stewardship of VHCURES 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, disclosure, and redisclosures of VHCURES data.

Data Linkage Request Process

This Data Linkage Request Form (DLRF) must be filed by agencies and organizations with DUAs wanting to link the VHCURES data with any identifiable record-level data sources (records with personally identifying information (PII)) or other data sources that could result in the identification of individuals in the VHCURES data set. DVHA will review requests for linkages that include Medicaid data. The GMCB must approve all requests for these linkages before the linkages are performed by data users. Unauthorized linking of VHCURES data with other data sources without prior approval of the GMCB could result in forfeiture of the DUA. Entities responsible for disclosures of VHCURES data with PII will be subject to civil and criminal sanctions under applicable state and federal laws and regulations.

Requestors (Vermont state agencies or non-state entities with VHCURES DUAs) must provide a list of data sources to which the VHCURES data would be linked and identify which data sources include personally identifiable information including the specific identifiers within those data sources.

The Principal Investigator (PI) identified on the DUA must ensure that Individual User Affidavits (IUAs) are filed with GMCB for all data users involved in the data linkage project who have not already filed IUAs under the DUA. When signing the IUA, each data user attests to understanding the appropriate use and disclosure of the data set and agrees to comply with the requirements.

If after reviewing the DLRF GMCB disapproves any data linkages, the GMCB will provide a written explanation to the requesting organization holding the DUA identifying the reasons for denying any data linkages.

General Instructions

Requestors must complete all required sections of the DLRF and submit an electronic copy of the completed request form, including all attachments, to gmcb.data@vermont.gov

Incomplete forms will not be reviewed until the requestor has provided all required information. A checklist is provided to help ensure that your form is complete. For questions about the data linkage request process, contact 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 an organization or agency that is applying or has obtained a data use agreement (DUA). The AU signatory on the DUA has 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 and organizations may designate multiple data custodians for different departments and programs. The data custodian(s) typically coordinate the receipt of the approved data set from GMCB's data consolidation vendor. The principal investigator may also be the data custodian. External agents approved by the GMCB through this Data Redisclosure Request Form to receive the data set or custom extracts must identify and file contact information for their data custodian(s) with the GMCB.

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. It is important to recognize that non-PII can become PII whenever additional information is made publicly available when combined with other available information.

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

Principal Investigator (PI): The Principal Investigator (PI) 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 VHCURES DUA. The PI 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.

Requestor: The requestor is the Vermont state agency, organization, or entity requesting authorization from the GMCB to re-disclose the VHCURES data available under the data use agreement (DUA) to an external agent to perform work directed and funded by the Requestor. External agents may include contractors, subcontractors, grantees, sub-grantees, and other types of entities as identified by the GMCB.

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

State Entity: Vermont agencies, contractors, or other organizations performing work directed and partially financed by the State of Vermont.

Data Linkage Request Checklist

(For use by the Requestor. Requestors must include all required attachments and applicable optional attachments)

Completed Form

- Data Linkage Project Description Including External Data Sources
- Linkage Data Management Plan
- Data Linkage Project Team
- Signatures

Required Attachments

- Attachment 1:** If this linkage project requires a redisclosure of VHCURES data to an external agent (contractor, subcontractor, grantee, sub-grantee), you must file a VHCURES Data Redisclosure Request Form unless one has already been filed and approved by the GMCB.
- Attachment 2:** If applicable to this data linkage request, attach Institutional Review Board approval document pertaining to the project for which the VHCURES data would be linked with other identifiable data sources.
- Attachment 3:** Other materials that may be requested by the GMCB for reviewing this form.

July 15 th 2020
Linkage Project End Date (Indicate if the project will be ongoing for the term of the DUA): 5 years after linkage occurs
Does the linkage project require redisclosure of VHCURES data to an external agent? <input checked="" type="checkbox"/> No- Skip the External Agent Information Section below. <input type="checkbox"/> Yes- Complete the External Agent Information section below. You must file a VHCURES Data Redisclosure Request Form or already have had the data redisclosure approved by the GMCB.
EXTERNAL AGENT INFORMATION
External Agent's Project Lead- Name and Title (External agent to whom VHCURES data would be redisclosed for the to support the data linkage project):
External Agent's Organization or Company Name:

Description of Data Linkage Project

Answer the following questions about the project that requires linkage of VHCURES data with other data sources.

1. Summarize the purpose and objectives of the proposed research requiring linkage of VHCURES data with other data sources.

Mortality is a key measure of population health and is a primary outcome for measuring provider quality and the impact of health policy changes targeting the affordability and effectiveness of health care services. While VHCURES includes a measure of hospital mortality, there is no way to accurately identify mortality in the community which limits rigorous study of the innovative medical and policy interventions in Vermont. Adding comprehensive mortality information to VHCURES will achieve several goals. First, more rigorous evaluations of prior and future medical/policy interventions will be possible. Second, because VHCURES includes claims from multiple payers, adding mortality information will allow for survival comparisons across payers that will elevate APCD research on Vermont nationally. Third, mortality will help identify health plan enrollment periods and when we can comprehensively identify the utilization history of beneficiaries in VHCURES. Moreover, we believe that adding comprehensive mortality information to VHCURES will lead to increased use of these data. To name just a few projects where it will have enormous impact, the Center for Health Services Research (CHSR) is currently pursuing research on:

- 1) The effectiveness of post-discharge care following intensive care stays in Vermont hospitals;
 - 2) Evaluating the impact of provider payment reforms- specifically, examining the ACO and community health team impacts on service utilization and health outcomes.
2. List and describe identifiable record-level data source(s) (records with personally identifiable information (PII)) you are planning to link with VHCURES data. List all personally identifiable information in the external data sources that would be linked with the VHCURES data. may Explain the matching methodology for linking the data. If the VHCURES records could become identifiable during the linkage process, explain how the identity of individuals and their PHI will be protected from potential opportunities for disclosure.
- Vital Records, specifically the death certificate, contains detailed demographic information and important details about the manner, cause, and location of a death. We plan to provide the following fields so that OnPoint can use their proprietary hashing algorithm and deidentify the death data that we can link with VHCURES information. These elements include:
- First Name,
 - Last Name,
 - Social Security Number,
 - Date of birth,
 - Gender.
3. Explain whether the proposed linkage project was review and approved by an Institutional Review Board (IRB). If yes, attach the IRB approval document as Attachment 2 to this form.
- This data would be used for variety of CHSR projects, and each analysis will be subjected to individual IRB reviews for secondary data analysis through the UVM IRB. We also are awaiting approval from the AHS IRB for approval of the data linkage.

VHCURES Data for Linkage with Other Data Sources

Indicate the VHCURES data files that would be linked for this project.

File Type	Commercial Insurers	Medicaid ¹		Medicare ²	Data Subset Specifications: Date Range and Gender, Age, Other Cohorts as applicable. ³
Medical Eligibility-VT Residents	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	
Medical Claims-VT Residents	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	
Medical Eligibility- 5% National Sample	Not applicable	Not applicable		<input type="checkbox"/>	
Medical Claims- 5% National Sample	Not applicable	Not applicable		<input type="checkbox"/>	
Pharmacy Eligibility	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		Not applicable	
Pharmacy Claims	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		Not applicable	
Medicare Part D Event - VT Residents	Not applicable	Not applicable		<input type="checkbox"/>	
Medicare Part D Event - 5% National Sample	Not applicable	Not applicable		<input type="checkbox"/>	
Medicare MEDPAR	Not applicable	Not applicable		<input type="checkbox"/>	

¹ The Department of Vermont Health Access (DVHA) must approve uses and disclosure of Medicaid data..

² Medicare data may only be used for research directed and partially funded by the state of Vermont.

³ Refers to Custom Extracts defined under Definitions in this form supporting the data stewardship principle of using the "minimum necessary" data to support the stated research purpose of the project.

Linkage Data Management Plan

Section 2 relates to the policies and procedures to ensure the proper management of VHCURES data that may include personally identifiable information after being linked with other data sources. The GMCB recognizes the applicability of best practices for information security and privacy used in the CMS Data Privacy Safeguard Program (DPSP)¹. Respond to every question about the technical and administrative safeguards over the data.

Physical Possession and Storage of Data Files

4. Describe how the Principal Investigator and project leads will maintain an accurate and timely inventory of the users and locations of VHCURES data and any derived files that may contain personally identifiable information.

The principal investigator will adhere to similar standards of protection that are currently followed by all VHCURES users at UVM (refer to the UVM VHCURES Procedure Manual for details). Anyone accessing the linked data files will need to also have approval utilize VHCURES data under the current Data Use agreement. VHCURES access is overseen by a Stewardship Committee at UVM. The stewardship committee regularly maintains rosters of data users and the scope of work for projects utilizing VHCURES. Only those listed on the scope of work and IRB for this linkage project would be granted access to the secure files for data analysis. Furthermore, study staff would only have access to information they need to view to complete the duties of their role. This means that study team member who need access to raw data would be granted this level access for either analysis or compiling aggregate results.

5. Describe any training that linkage project staff have had on protection of sensitive data with personally identifiable information protected health information, and other sensitive financial, economic, and personal information.

All project staff must be up to date with certifications for Research with Human Subjects and a training on Good Clinical Practice. Both trainings must be updated every 3 years. All trainings through UVM are completed through CITI.

6. Describe the protocol that would be followed by the linkage project staff to report and mitigate a breach in the security of data with personally identifiable information.

The University of Vermont has a Data Breach Notification policy to which all study personnel would adhere. This policy outlines how an incident should be reported, contained, investigated, and remedied. It also outlines the documentation process and communication for cases of data breach (policy attached for

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

reference). Data would be stored on a server that could only be accessed via VPN, with two factor authentication, which does not allow internet access when accessing server data (this is outlined in more detail in the UVM VHCURES procedure manual).

7. What actions will be taken to physically secure the data files that may contain PII during or following the linkage? This includes files on servers, local workstations, and hard media.

College of Medicine Information Technology (COMIT) has established a computer environment to support warehousing and analysis of VHCURES data. The Secure Environment for Data and Research Computing (SEDRC) is configured based on one of three security tiers (confidential, restricted, and prohibited) as defined by UVM information security policies. The VHCURES data are housed within this environment on Prohibited systems, the most secure. Systems have been deployed to support VHCURES and other work with sensitive data: An analytics server running statistical software, a data storage server running Microsoft SQL, and a secure file transfer server running Accellion Kiteworks. Approval from the VHCURES Data Stewardship Committee is required to gain access to these systems. All linked data will also be kept within the secure SEDRC environment for all analysis. (This is also discussed in more detail in the UVM VHCURES procedure manual).

8. Please explain if there is any plan to transmit, store, or transfer the data set or any derived files following the linkage between files outside the continental United States.

Researchers do not plan to transmit, store, or transfer the data outside of the United States.

Data Sharing, Electronic Transmission, Distribution

9. Describe what the policies and procedures will be for sharing, transmitting, and distributing the VHCURES data set and any derived files that may include PII with members of the linkage project team.

A project folder will be created on SEDRC. Only those staff who need to see raw data for analysis will be given access to this folder. Aggregated results can be shared with other members of the study team where appropriate and through the Kiteworks secure transfer server. Aggregated results will not be identifiable and will be suppressed if numerator or denominator sizes are too small. All aggregated results needed for presentations or publications will be stored in folders with limited access on a shared drive within the College of Medicine's environment.

10. The GMCB's preferred method of transmission of the data files is through a secure File Transfer Protocol (SFTP) transmission. If you anticipate requesting or transferring files for this linkage project via encrypted hard media, please explain the reasons that SFTP is not an option.

Data can be transmitted via SFTP to our secure server.

11. Describe methods for tracking, monitoring, and auditing access and use of the VHCURES data set or derived extracts of the data set in use for this data linkage project.

For this data linkage project, we will replicate our current arrangement for access to VHCURES. Members of the study team will be required to sign an affidavit and adhere to the current policies outlined in the UVM VHCURES procedure manual (attached) from the internal data stewardship committee. We will also keep our internal VHCURES stewardship committee apprised of this linkage project and how the data is used. Permissions to SEDRC are managed by the Larner College of Medicine (LCOM) IT staff. The Principal Investigator is responsible maintaining a roster of active staff who should have access to the data. At the time that someone should be removed from a study, the Principal Investigator is responsible for informing LCOM IT to change the credentials of members no longer working on the study.

12. Describe the policies and procedures and procedures that will be used to define data access privileges for individual users of the data, including the project leads, data custodians, analysts and researchers, and IT support.

We will follow the same process outlined for any VHCURES data user (refer the UVM VHCURES procedure manual). The linked data files will only be accessible to those approved to view raw data by the Principal investigator. At this time, this would only include those team members who need to see the data to complete the analyses.

13. Explain your 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).

UVM has an IT policy for general use of University hardware, require passwords and proper safeguarding of physical equipment (refer to attached Information Security Procedures). In addition to standard security process all data is housed and analyzed in an environment with additional protection. The SEDRC system is only accessible to approved personnel and require two factor authentication. It requires users to access a remote desktop through a secure VPN and limits access to the internet when the you are in the SEDRC environment. The application servers are configured to only talk to their specific data services. The SEDRC system will disconnect after periods of inactivity and requires the user to log back in via two factor authentication. The Principal Investigator is responsible for maintaining the project roster and keeping the LCOM IT department updated on who has appropriate access. For additional detail on these processes please see the attached UVM Information Security protocol and the VHCURES procedure manual from the Larner College of Medicine's data stewardship committee.

14. If additional copies of the VHCURES data used in this linkage project will be housed in separate locations, please describe how the data will be transferred to these locations.

All raw data files will be housed in SEDRC. Data results that will be disseminated either via presentation or publication will be transmitted from SEDRC to a shared drive within the College of Medicine network that can only be accessed by the study team. (Refer to the VHCURES procedure manual for more information).

Completion of Research Tasks and Data Destruction

15. Describe how the PI for the DUA will complete the Certificate of Data Destruction for the data and derived files used in this linkage project will be deleted, destroyed or rendered unreadable upon completion of the project.

Researchers would like to have access to the linked data for 5 years. As this is one of the early attempts of this type of data linkage, the researchers feel they need time to establish the linkage and learn about the intricacies of the data. This will also allow for enough time to utilize the data to answer the research questions about patterns in care for individuals from different geographic areas over time (and through changing screening guidelines). After 5 years, depending on utilization and success in publishing results we may request another extract and/or extended access to the initial data extract.

16. Describe the policies and procedures that will be used to protect the data and derived files from this linkage project when individual members of the project team terminate their participation in this project.

We are beholden to all University of Vermont policies on data privacy and protection (refer to the attached data breach policy and the Information Security). Furthermore, the Larner College of Medicine (LCOM) IT team has established a computer environment to support warehousing and analysis of this level of sensitive data. The Secure Environment for Data and Research Computing (SEDRC) is configured based on one of three security tiers (confidential, restricted, and prohibited) as defined by UVM information security policies. We would propose keeping the linked data in a prohibited system. This would require data is stored on encrypted volumes, transferred over encrypted connections, and cannot leave the environment unless approved by the Principal Investigator. Access to any of the data is limited to research study personnel performing the data analysis. The Principal Investigator is responsible for maintaining the roster of study personnel who have access to the data and communicating this with the LCOM IT staff. (Refer to the VHCURE procedure manual attached for further description).

Data Linkage Project Team

Data Linkage Project Lead (From agency or organization with the GMCB VHCURES DUA)

Please provide contact information for the project lead for data linkage as identified in the table under 1-1 in this form.

Name and Title of the Data Linkage Project Lead		
Caitlyn Dayman; Researcher/Analyst at the Center for Health Services Research		
Project Lead's Agency or Organization Name		
Larner College of Medicine, UVM		
Street Address		
89 Beaumont Ave		
City	State	Zip
Burlington	VT	05405
Telephone	Email	
802-656-8704	Caitlyn.dayman@med.uvm.edu	

Data Custodian(s) for Data Linkage Project

Please provide contact information for the data custodian(s) who will be storing and managing the VHCURES data set or derived files during and following the data linkage.

Name and Title of Data Custodian		
Steve Goldman; Manager, Database and Application Services		
Organization		
Larner College of Medicine, UVM		
Street Address		
89 Beaumont Ave		
City	State	Zip
Burlington	VT	05405
Telephone	Email	
802-656-9770	Stephen.goldman@med.uvm.edu	

Name and Title of Data Custodian		
Adam Atherly; Director of the Center for Health Services Research		
Organization		
Larner College of Medicine, UVM		
Street Address		
89 Beaumont Ave		
City	State	Zip
Burlington	VT	05405
Telephone	Email	
802-656-3555	Adam.atherly@med.uvm.edu	

Name and Title of Data Custodian		
Organization		
Street Address		
City	State	Zip
Telephone	Email	

Individual Users

List the anticipated individual data users for the data linkage project including internal agency/organization staff and contractors and subcontractors, grantees, and sub-grantees and their roles in the project. Signed IUAs for individual users must be filed prior to the VHCURES data linkage and anytime during the project. You are not required to file new IUAs for state employees or employees of non-state entities who have already filed IUAs under current VHCURES DUAs.

Name	Organization	Project Role or Title
Adam Atherly	UVM	Co-Investigator
Sarah Nowak	UVM	Co-Investigator
Andrew Wilcock	UVM	Co-Investigator
Stephen Goldman	UVM	Information Systems Support
Caitlyn Dayman	UVM	Research Analyst

Signatures

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

DUA Principal Investigator (Requestor)/Name:	
Signature:	Date:

Data Linkage Project Lead Name (if different from Principal Investigator):	
Signature:	Date:

GMCB Processing Section

For GMCB Use Only

VHCURES Data Linkage Project Request Form received: Click or tap to enter a date.

DVHA Medicaid Data Linkage Approval Date (Applicable to Medicaid data): Click or tap to enter a date.

GMCB overall comments:

Approved and no further action is required: Click or tap to enter a date. **9/30/2020**

Approved with Conditions: Click or tap to enter a date.
Describe conditions that must be met prior to term extension:

Not Approved: Click or tap to enter a date.
Describe reasons for disapproval of term extension:

Date Requestor Notified: Click or tap to enter a date. **9/30/2020**