

VHCURES Data Redisclosure 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 review and approve all requests from state agencies and other organizations to redisclose the data set and data extracts under existing DUAs to external entities such as contractors, subcontractors, grantees or sub-grantees. GMCB has the discretion to approve or disapprove redisclosures of commercial and Medicare data and shares discretion with DVHA regarding redisclosures of Medicaid data.

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 re-disclosures of VHCURES data.

Redisclosure Request Review Process

This Data Redislosure Request form is required for all requests from agencies and organizations with VHCURES DUAs to redisclose the VHCURES data set to external agents such as contractors, subcontractors, grantees, and sub-grantees. The GMCB must approve all requests for redisclosures of the data set and extracts generated from the data prior to any re-disclosures. Unauthorized redisclosures of the data without prior approval of the GMCB may be considered a breach. Entities applying for or in possession of a DUA risk forfeiture of the DUA and the data if unauthorized disclosures occur under their DUAs with the GMCB. Entities responsible for unauthorized redisclosures may be subject to civil and criminal sanctions under applicable state and federal laws and regulations.

GMCB staff must deem this form complete before initiating the review process. **This includes submission of all required and optional attachments as listed in the Data Redislosure Request Checklist in this form.**

Requestors (Vermont state agencies or non-state entities with VHCURES DUAs) must provide a full list of individuals who will have access to the data set upon the effective date of an approved redisclosure. If this form is being filed with a DUA application, the applicant will have provided a list of data users in the application. The Principal Investigator (PI) identified on the DUA must ensure that Individual User Affidavits (IUAs) are filed with GMCB for all data users prior to their access to the data set any time during the term of the DUA or risk forfeiture of the DUA and the data set. 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.

After a Data Redislosure Request is deemed complete, GMCB will start the review process and either approve or disapprove redisclosures of the data. DVHA may review requests for redisclosures that include Medicaid data. This process seeks to ensure continued compliance with provisions of state and federal laws, regulations, and agreements regarding use and disclosure of the data.

If after reviewing the Data Redislosure Request GMCB declines a redisclosure of data, the GMCB will provide a written explanation to the requesting organization holding the DUA identifying the reasons for denying a redisclosure of the data.

General Instructions

Requestors must complete all required sections of the Data Redislosure Request and submit an electronic copy of the completed request form, including all attachments, to gmc.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 Redislosure Request process, contact gmc.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.

Custom Extract: A custom extract includes the minimum necessary data to support the research purpose. A custom extract is a data subset or table generated from the standard comprehensive research data set with commercial, Medicaid, and Medicare data.

This process ensures continued compliance with the requirements of the DUA and particularly supports the concept of using the minimum necessary data to support the approved research purpose. For example, if an Authorized User with a VHCURES DUA hires a contractor to analyze VHCURES data for a study of pediatric asthma in the Medicaid population, the GMCB might only approve use of a custom extract that includes Medicaid paid claims data for enrollees under the age of 19.

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 Rediscovery Request Form to receive the data set or custom extracts must identify and file contact information for their data custodian(s) with the GMCB.

Data Rediscovery: Any Vermont state agency or non-state entity with a VHCURES DUA that intends to redisclose the VHCURES data set or any custom extracts of the data set to external agents to support projects approved under the DUA must file a Data Rediscovery Request Form (Data Rediscovery Request) with the GMCB for review and approval prior to the redisclosure.

After the GMCB has reviewed a Data Rediscovery Request and approved redisclosure of data to an external agent, the GMCB may request its data consolidation vendor to generate custom data extracts for external agent or permit the external agent to access the data enclave hosted by the vendor. Use of services provided by the GMCB's data consolidation vendor may require payment of a fee to the vendor.

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: 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 also be the Authorized User for the 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. For external agents such as contractors, the Project Lead as identified on the Data Redislosure Request Form reports to the PI identified in the DUA on matters pertaining to access 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 Redisclosure Request Checklist

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

Completed Form

- Redisclosure Summary
- Redisclosure Data Management Plan
- Redisclosure Project Team
- Data Procurement and Price
(May apply to external agents approved by the GMCB for custom extracts or access to the secure data enclave hosted by the GMCB's data consolidation vendor)
- Data Transmission and Receipt
- Signatures

Required Attachments

- Attachment 1:** Electronic copy of the state contract, subcontracts, grants or agreements between the authorized user with a VHCURES DUA and the entity to whom the data will be redisclosed if authorized by the GMCB.
- Attachment 2:** Data Governance and Protection Policies and Procedures of the external agent's organization(s) to which the VHCURES data will be redisclosed.

Optional Attachments Applicable to Proposed Data Redisclosures

- Attachment 3:** If applicable to this redisclosure request, attach a Data Linkage Request Form (provided by the GMCB) if the redisclosed VHCURES data will be linked with other identifiable record-level data sources or any other types of data that could result in reidentification of persons in the VHCURES data set (See 1-2-2 in this form).
- Attachment 4:** If applicable to this redisclosure request, attach Institutional Review Board approval document pertaining to the project for which the data will be redisclosed.
- Attachment 5:** Other materials that may be requested by the GMCB for reviewing this form.

REDISCLASURE REQUEST FORM

Redisclasure Summary

Describes the research project that requires the redisclasure of data to external agents under a VHCURES DUA. Answer every question in this section. If a question does not apply to the project, indicate that the item is “Not Applicable.” Do not leave a question blank or the form will be deemed incomplete.

Overview of Project Requiring Data Redisclasure

DATA USE AGREEMENT INFORMATION FOR REQUESTOR
DUA Identifier (Assigned by the GMCB to the DUA):
DUA Agency or Organization Name (Not the name of the organization or external agent to whom the data would be redisclasured):
DUA Project Name (As stated in the DUA application or DUA):
DUA Authorized User Signatory Name & Title:
DUA Principal Investigator Name & Title (if different from Authorized User):
Project Contact’s Name and Title (Contact managing the project for the organization with the DUA):
Brief Description of the Project Requiring the Data Redisclasure (Summary of subsection 1-2-1):
Project Start Date (Contract, grant or agreement start date):
Project End Date (Contract, grant or agreement end date):
Funding Source(s) for the Project Requiring Data Redisclasure: <input type="checkbox"/> State <input type="checkbox"/> Federal <input type="checkbox"/> Other
Identify Funding Sources by Names of Agencies and Organizations:
Vermont State Contract # (if applicable):
Electronic Link to Vermont State Contract (if applicable):
If the VHCURES DUA is between GMCB and a non-state entity, an electronic copy of the contract between the non-state entity and the external agent must be filed as Attachment 1 to this form.
EXTERNAL AGENT INFORMATION
External Agent’s Project Lead- Name and Title (External agent to whom the data would be redisclasured):
External Agent’s Organization or Company Name:

Description of Data Redisclosure Project

Answer the following questions about the project that requires redisclosure of the VHCURES data.

1. Summarize the purpose and objectives of the proposed research requiring a redisclosure of VHCURES data. In reference to section 1-3 below, describe the “minimum necessary” data required to support the research purpose of this particular data redisclosure.
2. List and describe any identifiable record-level data sources (records with personally identifying information (PII)) you are planning to use in conjunction with the redisclosed VHCURES data. If VHCURES and other files will be linked in any way, explain the matching methodology for linking the data. If the VHCURES records will become identifiable during the linkage process, explain how the identity of individuals and their PHI will be protected from potential opportunities for disclosure.
3. Explain whether the proposed project was review and approved by an Institutional Review Board (IRB). If yes, attach the IRB approval document as Attachment 4 to this form.

Requested Data for Redislosure

4. Indicate the data files requested for redisclosure in this form.

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 type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Medical Claims-VT Residents	<input type="checkbox"/>	<input type="checkbox"/>	<input 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 type="checkbox"/>	<input type="checkbox"/>	Not applicable	
Pharmacy Claims	<input type="checkbox"/>	<input 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.

Redisclosure Data Management Plan

This section relates to the policies and procedures that the external agent’s organization will use to ensure the proper management of the redisclosed VHCURES data and extracts derived from the data set. 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

5. Describe how the external agent for the project will maintain an accurate and timely inventory of the users and locations of redisclosed VHCURES data and any derived files.
6. Describe the procedures that the external agent for the project will take to track the status and roles of the research team and notify the Principal Investigator (PI) for the DUA about project staffing changes.
7. Describe how the external agent trains and educates project staff on how to protect sensitive data with personally identifiable information, protected health information, and other sensitive financial, economic, and personal information.
8. Describe the protocol that would be followed by the external agent to report and mitigate a breach in the security of the redisclosed VHCURES data. Who will be responsible for notifying the Principal Investigator (PI) for the DUA who is required to notify the GMCB and CMS, as applicable to Medicare data, of any suspected incidents of a breach in the security of the VHCURES data?
9. What actions will the external agent take to physically secure the data files? This includes files on servers, local workstations, and hard media.
10. Please explain if the external agent 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

11. Describe what the external agent's policies and procedures will be for sharing, transmitting, and distributing the VHCURES data set and any derived files with members of the project team.
12. The GMCB's preferred method of transmission of the data files is through a secure File Transfer Protocol (SFTP) transmission. If the external agent anticipates requesting or transferring files via encrypted hard media, please explain the reasons that SFTP is not an option.
13. Would the external agent be interested in accessing a hosted data enclave eliminating the transmission of data files via SFTP or via encrypted hard media? If not interested, please explain concerns of the external agent.
14. Describe the external agent's methods for tracking, monitoring, and auditing access and use of the redisclosed VHCURES data set or derived extracts of the data set.
15. Describe the policies and procedures and procedures the external agent uses to define data access privileges for individual users of the data, including the Project Lead, data custodians, analysts and researchers, administrative support, and IT support.
16. Explain the external agent's 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).
17. Describe how the external agent will access the redisclosed data, e.g., VPN connection, travel to your organization, or house the data at other locations.
18. If additional copies of the redisclosed data will be housed by the external agent in separate locations, please describe how the data will be transferred to these locations.

Data Reporting and Publication

19. Explain your process for reviewing publications produced by external agents prior to dissemination to ensure accurate and appropriate representation of data sources and disclaimers. Describe how publications produced by external agents 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

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

21. Describe the external agent's policies and procedures that will be used to protect the redisclosed data and derived files when individual members of the project team terminate their participation in research projects.

Redisclosure Project Team

Primary Contact (External Agent for Data Redisclosure)

Please provide contact information for the primary contact for the external agent as identified under 1-1 Project Overview information table in this form.

Name and Title of the Primary Contact		
External Agent's Organization Name		
Street Address		
City	State	Zip
Telephone		Email

Project Lead/Principal Investigator (External Agent for Data Redisclosure)

Please provide contact information for the person leading the project and acting as the principal investigator for the external agent. Just include the name if the Project Lead/PI is also the Primary Contact.

Name and Title of Project Lead/Principal Investigator		
Organization Name		
Street Address		
City	State	Zip
Telephone		Email

Data Custodian(s) (External Agent for Data Rediscovery)

Please provide contact information for the external agent's data custodian(s) who will be storing and managing the VHCURES data set or derived files.

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

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

Name and Title of Data Custodian

Organization

Street Address

City	State	Zip
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Telephone	Email
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Data Procurement and Price

There will be no fee charged to state agencies that receive the data set via a secure file transfer protocol (SFTP). The authorized user will receive the data from the GMCB's designated data processing vendor.

In the future, the GMCB may be offering access to the data through a hosted data enclave. This would eliminate or be an additional option for accessing the data via electronic SFTP transmission of the record-level data. GMCB will notify the authorized user for the DUA when this service becomes available as an option and how it will work as to number of user seats and pricing.

There will be a fee for extracts generated from the VHCURES data set as requested by the authorized user for redisclosure to external agents authorized by the GMCB to receive the data. The GMCB strictly prohibits the transmission or shipping of copies or derived extracts of the VHCURES data set to external agents. Custom extracts can be generated to support the data stewardship principle of disclosing the minimum necessary data to support the research purpose. Use of consulting services provided by the GMCB's data consolidation vendor may require payment of a fee to the vendor. Onpoint Health Data will manage any invoicing for charges.

The GMCB's designated vendor for the VHCURES Research Data Set is:

Onpoint Health Data

Mailing Address:

75 Washington Avenue, Suite 1E
Portland, ME 04101

Physical Address:

55 Washington Avenue
Portland, ME 04101

Main Phone: (207) 623-2555

www.onpointhealthdata.org

Data Transmission and Receipt

Use of an electronic secure File Transfer Protocol (SFTP) is the preferred mode of release for approved data extracts. Onpoint Health Data, the GMCB's data consolidation and warehousing vendor will provide an "Electronic Data Transmission Readiness and Logistics Checklist" to assist external agents to determining readiness to receive the transmission.

Please identify your primary contact below for setting up the logistics for SFTP 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.

As noted under Section 4, the GMCB may offer access to the data via a hosted data enclave in the future. Authorized users will be notified when this service becomes available.

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:

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:

Project Lead for the External Agent/Name:	
Signature:	Date:

GMCB Decision

For GMCB Use Only

Date the Data Redisclosure Request filed with GMCB:

Date Data Redisclosure Request Form Deemed Complete/GMCB Reviewer Name:

DVHA Medicaid Data Redisclosure Approval Date (If applicable):

GMCB Data Redisclosure Approval Date/GMCB Approver Signature:

Date Requestor Notified of Approval:

Date Redisclosure Denial Date:

Date notified in writing of denial/GMCB Signature

Summary of reasons for redisclosure denial:
