Application for Non-State Academic and Non-Profit Entities:

VHCURES Limited Use Health Care Claims Research Data Set



144 State Street

Montpelier, VT 05620
802-828- 2177

[gmcboard.vermont.gov](http://gmcboard.vermont.gov)

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# APPLICATION INSTRUCTIONS

## Introduction

The Vermont Health Care Uniform Reporting and Evaluation System (VHCURES)

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 is required to make the VHCURES data and information available as a resource for individuals and entities to continuously review health care utilization, expenditures, and performance in Vermont to the extent permitted by the Health Information Portability and Accountability Act (HIPAA) and other pertinent state and federal laws.

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. Under a DUA between GMCB and CMS, GMCB has independent discretion to make decisions regarding the use and disclosure of the Medicare data subset by Vermont state agencies.

Vermont state agencies may apply for a standard comprehensive research data set that includes all unrestricted and restricted data elements for broad use internally and by state contractors. Non-state entities may apply for a DUA for a limited use health care claims research data set using a different application form. This type of data set excludes the Medicare data subset and is tailored to specific research purposes as approved by GMCB and DVHA if the Medicaid data subset is requested. Applicants who are non-state entities must justify requests for individual restricted data elements and explain how the requested restricted data elements are applicable to the intended research purpose.

Data Governance Council

The GMCB chartered the [Data Governance Council](http://www.gmcboard.vermont.gov/VHCURES/DataGov) (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 DCG supports the GMCB decision-making process for applications requesting use and disclosure of VHCURES data sets by non-state entities as addressed in this application form.

## Application Review Process

This application is required of non-state entities requesting a DUA for a VHCURES limited use health care claims research data set (hereafter referred to as a limited use research data set) with the option of including the commercial and Medicaid data subsets 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.

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. All requests for the Medicaid data subset must also be approved by the Department of Vermont Health Access (DVHA). The GMCB will provide DVHA with a copy of the complete application, following a review of the application by the GMCB. Applicants may also be required to obtain approval of the AHS Institutional Review Board (IRB) Committee. (See http://humanservices.vermont.gov/boards-committees/irb)

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 and DVHA, if applicable, have approved the application for a DUA.

The GMCB must review and approve requests by non-state entities to redisclose data including custom extracts to contractors, subcontractors, or other external agents. Non-state entities must file data redisclosure request form(s) (DRRF) with the GMCB prior to redisclosing the data set or any extracts generated from the data set to any external agents. This ensures continued compliance with provisions of state and federal laws and regulations regarding the data. The GMCB must also review any proposal to change the use or research purpose of the data after the DUA has been issued for a specific research purpose. The GMCB may require the filing of a new application for a DUA after reviewing requests for change in data use under an existing 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, GMCB, and DVHA if the Medicaid data subset is included. 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 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 including those of DVHA if Medicaid data are being requested. 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 gmcb.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.

***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 commercial and Medicaid data subsets. The Medicare data subset is only available to Vermont state agencies under the data use agreement between CMS and the GMCB.

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 the study approved under a VHCURES DUA addresses pediatric asthma in the Medicaid population, the GMCB may approve use of a custom extract that includes Medicaid paid claims data for enrollees under the age of 19 only.

***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 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. State contractors or other agents approved by GMCB to receive the data set or custom extracts after a review of a Data Redisclosure Request Form must identify and file contact information for their data custodian(s) with the GMCB.

***Data Redisclosure:*** 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 Redisclosure Request Form (DRRF) with the GMCB for review and approval prior to the redisclosure.

After the GMCB has reviewed a DRRF and approved redisclosure of data to an external agent, the GMCB may request its data consolidation vendor to generate custom data extracts for external agents 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 (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 Procurement and Price

 [ ]  **Section 5**: Data Transmission and Receipt

 [ ]  **Section 6:** Signatures

**Required Attachments**

[ ]  **Attachment 1:** Data Use Agreement template (*Will be signed by the Authorized User and Principal Investigator after the application is approved by Agency of Digital Services for Agency of Administration, GMCB, and DVHA (if Medicaid data is to be disclosed under the DUA*)

 ☐ **Attachment 2:** Entity’s Data Governance and Protection Policies and Procedures

☐ **Attachment 3:** Limited Use Research File Specification (Includes justification for requesting restricted data elements as necessary to support the specific research purpose)

**Optional Attachments Applicable to Proposed Redisclosures of the Data or Extracts**

☐ **Attachment 4**: Copy of proposed contracts, subcontracts, or any other agreements with external agents requiring redisclosure of the data set or custom extracts

☐ **Attachment 5:** Data Redisclosure Request Form(s) (DRRF) must be filed for every external agent identified under Attachment 4 to whom the data or data extracts will be re-disclosed by the entity in possession of the DUA

☐ **Attachment 6:** Data Governance Policies and Procedures for every external agent identified under Attachment 4 that will be receiving and managing the data set or extracts of the data set

**Miscellaneous Optional Attachments**

**☐ Attachment 7:** If applicable to this application, Institutional Review Board approval document

☐ **Attachment 8:** Other materials requested by the GMCB for the purpose of reviewing the application

### APPLICATION

### Section 1: Research Summary

Section 1 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: Dr. Daniel Zoughbie |
| Organization/Entity Name: Hammurabi Insurance Services, Inc., University of California, Berkeley SkyDeck, 2150 Shattuck Ave, Berkeley, CA 94704 |
| Type of Organization  | ☐ Federal or State government entity outside of Vermont☐ Contractor of Federal or State government entity outside of Vermont☐ Academic Institution☐ Non-profit research organization☐ Participant in the Vermont health care system financing, insurance, or delivery system with direct impacts on the Vermont population☐ Participant in health care financing, insurance or delivery systems outside of Vermont☐ Health care enterprise such as manufacturers or distributors of pharmaceuticals and medical technology; designers and developers of health systems and facilities, etc. X Other: Please describe belowWe are a start-up run by university scientists based out the University of California, Berkeley SkyDeck accelerator program.  |
| Principal Investigator Name & Title (if different from Authorized User):Dr. Kyongsik Yun |
| Project Name (Specify a topic or study):Predictors of high-cost medical utilization and comorbidity burden among US individuals with public and private insurance |
| Brief Project Description (Summary of subsection 1-5-1):Led by our team of faculty scientists, project Hammurabi is committed to address the rising costof healthcare in the United States. This rise threatens economic prosperity and fair andequitable delivery of healthcare. Further, a relatively small proportion of health plan membersoften drive health plan costs. Prevailing models of US health care delivery focus on treatmentrather than delivering primary or secondary prevention, which may lead to costly andunnecessary healthcare utilization. This study will entail a retrospective, administrative claimsanalysis utilizing pharmacy, medical, and eligibility data from public and private health insurersacross the US. All data will be de-identified before being transferred to the investigators.The aim of this project is two-fold: first, to explore causal pathways for diseases and associatedcomplications related to choices in the delivery of healthcare and health associated behaviors;and second, to understand how these potential causal pathways may affect healthcare costs.To address these research questions, we seek to analyze claims both at individual andpopulation levels to determine if there are key factors – such as age, sex, and geography --which may contribute to increased risk for certain conditions. The contribution of this researchwill be to help shape the way risk is understood and mitigated, including promoting thedeployment of targeted preventative healthcare interventions (such as risk management tools,strategies, and programs) to avoid costly and unnecessary healthcare utilization.We intend to explore opportunities for intervening early on Vermont residents to prevent andmanage major health incidents that are both costly and harmful to human flourishing. If we canpredict these incidents in advance, we can recommend strategies for mitigating these costs.With support from UC Berkeley’s SkyDeck program, we are committed to performing high quality scientific research and development and building an ecosystem of cost-savings solutions. Hammurabi is laser focused on improving health care in the US more generally and in Vermont, especially. Our eventual aim is to reduce the cost of health care in Vermont and in the US. Ifserious medical events can be predicted more accurately, targeted interventions can bedeployed to prevent and mitigate costs more quickly and effectively.Our research and development could shed light on health disparities, showing that certaingroups are more at risk. We hope for the opportunity to share some insights andrecommendations with the State of Vermont concerning how these more vulnerable groupscan be intervened upon with targeted interventions and outreach. |
| Project Start Date: November 15, 2022 or as soon as possible |
| Project End Date: November 15, 2032 |
| Funding Source(s)[ ] State [ ] Federal [x]  If Other, please describe:We received funding via the University of California, Berkeley SkyDeck program. |
| Line of Business data subset included in data request:[x] Commercial [ ] Medicaid (DVHA must approve Medicaid data use) |
| If you intend to redisclose the data to contractors, subcontractors, or other external parties, identify parties (Must align with documents filed under Attachments 4, 5, and 6): |

### Authorized User Acknowledgements

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

|  |  |
| --- | --- |
| ( X ) | *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).* |
| ( X ) | *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.*  |
| ( X ) | *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.* |
| ( X ) | *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 the VHCURES data set. 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.* |
| (X ) | *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.* |

### Project Questions

*Answer the following questions about your research project.*

|  |  |
| --- | --- |
| Yes [ ]  No[x]  | Is the project directed by the State of Vermont including Vermont state agencies and UVM?  |
| Yes [ ]  No[x]  | Is this project partially or wholly funded by the State of Vermont? |
| Yes [ ]  xNo[ ]  | Will products generated from the project be used for a proprietary, commercial purpose to generate revenues and income? If yes, explain below:We believe that the insights from our research will be useful for a whole host of purposes, including to generate revenue for preventative interventions. For example, if we are able to predict who will develop a disease with greater precision, a range of public, private, and commercial entities could benefit from this. We could help them to identify at-risk individuals earlier and to suggest cost-efficient interventions that could prevent illness and save lives and money. |
| Yes [x]  No[ ]  | Is the project useful for determining the capacity and distribution of existing health care resources?  |
| Yes [x]  No[ ]  | Is the project useful for identifying health care needs and informing health care policy?  |
| Yes [x]  No[ ]  | Is the project useful for evaluating the effectiveness of intervention programs on improving patient outcomes?  |
| Yes [x]  No[ ]  | Is the project useful for comparing costs between various treatment settings and approaches?  |
| Yes [x]  No[ ]  | Is this project useful for providing information to consumers and purchasers of health care? |
| Yes [x]  No[ ]  | Is this project useful for improving the quality and affordability of patient health care and health care coverage?  |
| Yes [x]  No[ ]  | Does the project directly support public health activities? |
| Yes [x]  No[ ]  | 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 [ ]  X No[ ]  | Does this project propose to link VHCURES data with any other individual record-level data sets? *If yes*, describe the data sets and proposed methodology for linking in Section 1-5-4. We do not intend to link VHCURES identifiable record-level data files with other individually identifiable data. |
| Yes [ ]  No[x]  | Does this project anticipate re-disclosure of the data set, custom extracts 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? *If yes, file Attachment 4, 5, and 6.* |

### Requested Data

*Indicate the data files requested in this application.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **File Type** | **Commercial Insurers** | **Medicaid**1 | **Medicare**2 | **Data Years or Date Range**3 |
| Medical Eligibility-VT Residents |[x] [x]  Not applicable | All available. |
| Medical Claims-VT Residents |[x] [x]  Not applicable | All available. |
| Medical Eligibility- 5% National Sample | Not applicable | Not applicable | Not applicable | All available. |
| Medical Claims- 5% National Sample | Not applicable | Not applicable | Not applicable | All available. |
| Pharmacy Eligibility |[x] [x]  Not applicable | All available. |
| Pharmacy Claims |[x] [x]  Not applicable | All available. |
| [Medicare Part D Event](http://www.resdac.org/cms-data/files/pde)- VT Residents | Not applicable | Not applicable | Not applicable | All available. |
| [Medicare Part D Event](http://www.resdac.org/cms-data/files/pde)- 5% National Sample | Not applicable | Not applicable | Not applicable | All available. |
|  Medicare [MEDPAR](http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/IdentifiableDataFiles/MedicareProviderAnalysisandReviewFile.html) | Not applicable | Not applicable | Not applicable | All available. |

*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 VHCURES data are available on a consolidated CY quarterly or annual basis on paid claims date basis starting with CY 2007.*

### Project Overview

1-5-1. 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.

Led by a faculty scientist, project Hammurabi is committed to address the rising cost of healthcare in the United

States. This rise threatens economic prosperity and fair and equitable delivery of healthcare. Further, a relatively

small proportion of health plan members often drive health plan costs. Prevailing models of US health care delivery

focus on treatment rather than delivering primary or secondary prevention, which may lead to costly and

unnecessary healthcare utilization. This study will entail a retrospective, administrative claims analysis utilizing

pharmacy, medical, and eligibility data from public and private health insurers across the US. All data will be de-

identified before being transferred to the investigators.

1-5-2. 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.

Principal Investigator:

Dr. Kyongsik Yun is a computational neuroscientist who served as a CalTech research scientist for several years, he

is a world-authority on computational neuroscience. He is a published scholar in peer-reviewed journals, including

*Scientific Reports*, Nature Translational Psychiatry, Fronteirs in Cellular Neuroscience, Alzheimer’s Research and

Therapy, Frontiers in Psychiatry, Journal of Affective Disorders, PLOS One, and Electronic Imaging.

Authorized User:

Dr. Daniel Zoughbie was appointed an associate project scientist as UC Berkeley and specializes in the analysis of

complex systems, including social networks. He has published in The Lancet Global Health, PLOS Global Public

Health, JAIDS, Circulation, and Diabetes.

1-5-3. If your project requires the use of Medicaid data, is the research intended to support public health activities? If yes, explain the application of the project to public health. If no, you may be required to obtain approval to use the Medicaid data from the AHS IRB Review Committee in addition to DVHA. See Optional Attachment 6.

NA

1-5-4. 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.

We will be using all of the data requested in the course of our research. We will not be requesting data that is outside the scope of our research.

1-5-5. 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 VHCURES data. If the files will be linked, explain the methodology for linking the data; if applicable, which files include direct personal identifiers and list the personal identifiers included in the files; and how the identity of individuals and their PHI will be protected from unauthorized disclosures within and outside your agency or organization.

We do not intend to re-identify any de-identified data. Further, we do not intend to link VHCURES identifiable record-level data files with other individually identifiable data.

* + 1. 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.

Hammurabi’s funding for this project comes from the University of California, Berkeley’s SkyDeck program and fund.

* + 1. Explain whether any component of the project was review and approved by an Institutional Review Board (IRB)**.** If yes, attach the IRB review and approval under Attachment 7 to this application.

Yes, please see attached.



Section 2 relates to the policies and procedures your organization will use to ensure the proper management of the VHCURES limited use research data set and custom 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 to the review of VHCURES 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 including relevant page and/or section numbers. **Do not simply cite a cross-reference to the policy and procedure documents included under Attachment 2 and 6 of this application in lieu of answering each question. If questions are not answered completely, the application will be deemed incomplete.**

Any Data Redisclosure Request Forms (PRF) filed with this application for external agents under Attachment 5 may cite cross-references to this application for the same items in Section 2 below. Instructions are included on the DRRFs.

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

### 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****.*

*See attached policy.*

* + 1. Describe how your organization will maintain an accurate and timely inventory of the VHCURES limited use research data set including original files received and any derived files used within your organization or released to external agents under state contracts and agreements.

Data will be used by one professional researcher with experience handling large and confidential datasets. Data will be stored in a secure environment. Researcher will keep the files in one physical location.

* + 1. 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.

Researcher access to data will be logged. Data will not be sent to external agents.

* + 1. 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.

If there are any staffing changes, we will promptly notify GMCB of such changes. We do not anticipate any changes at this time.

* + 1. 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.

Researcher is a trained professional University researcher.

* + 1. 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 (and CMS as applicable to Medicare data available only to Vermont State Agencies and agents of the State) of any suspected incidents of a breach in the security of the VHCURES data?

Researcher will be responsible for conducting research in accordance with protocol.

* + 1. 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.

Data will be kept in a physically locked file if transmitted to us as a hard drive. Data will be kept in a password protected environment at all time. We are requesting the minimal amount of data needed to perform our research.

* + 1. Please explain if your organization intends to transmit, store, or transfer the data set or any derived files outside the continental United States.

NA

### 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.***

* + 1. Describe what your organization’s policies and procedures will be for sharing, transmitting, and distributing the VHCURES data set and any derived files.

 **See attached.**

* + 1. The GMCB’s preferred method of transmission of the data files is through a secure File Transfer Protocol (SFTP) transmission. If you anticipate requesting encrypted hard media, please explain the reasons that SFTP is not an option.

**SFTP is fine.**

* + 1. Would your organization and approved external agents be interested in accessing a hosted data enclave or a researchers’ workbench environment eliminating the transmission of data files via SFTP or via encrypted hard media outside of the hosted enclave? If yes, would the interest hold if there are fees for this service? If not interested at all or cautious, please explain your concerns.

**No.**

* + 1. Describe your organization’s methods and those of approved external agents for tracking, monitoring, and auditing access and use of sensitive data such as the VHCURES data set.

**You have to sign in to get into the computer and access the data. Also, the room is physically locked. Device access will be restricted to only authorized personnel.**

* + 1. 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.

**Only those listed on the application will have access.**

* + 1. 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).

**See attached.**

* + 1. 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.

NA

* + 1. 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.

NA

### Data Reporting and Publication

* + - 1. 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.

**If we publish anything, we will seek the review of your department first. We will always ensure that any published or accessible presentation of data is encrypted to the level that it cannot re-identify a person.**

### Completion of Research Tasks and Data Destruction

* + 1. 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.

Data will be destroyed per user agreement and extension will be filed if necessary.

* + 1. Describe your organization’s policies and procedures and those of external agents used to protect VHCURES 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).

Only authorized users will have access. However, if staff no longer work for us, their physical and digital access will be revoked and they will no longer have access to the files.

* + 1. 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.

Data will be destroyed per agreement.

## Section 3: Project Team

In Section 3-4, 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 the VHCURES data set 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.*

|  |
| --- |
| N Name and Title of Signatory for the Authorized User |
| Dr. Daniel E. Zoughbie |
| Organization Name Website |
| Hammurabi Insurance Services, Inc. |
| Street Address University of California, Berkeley SkyDeck, 2150 Shattuck Ave. |
|  |
| City Berkeley  | State CA | Zip 94704 |
|  |  |  |
| Telephone 6508236599 | Email danielzoughbie@gmail.com |
|  |  |
|  |

### Principal Investigator

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

 [x] Same as Authorized User Signatory

|  |
| --- |
| Name and Title of Principal Investigator 1 |
| Dr. Kyongsik Yun |
| Organization NameWebsite |
| Hammurabi Insurance Services, Inc. |
| Street Address University of California, Berkeley SkyDeck, 2150 Shattuck Ave. |
|  |
| City Berkeley | State CA | Zip 94704 |
|  |  |  |
| Telephone 6508236599 | Email danielzoughbie@gmail.com |
|  |  |

|  |
| --- |
| Name and Title of Principal Investigator 2 |
|  |
| Organization NameWebsite |
|  |
| Street Address |
|  |
| City | State | Zip |
|  |  |  |
| Telephone | Email |
|  |  |

### Data Custodian(s)

*Provide contact information for the data custodian for your organization and the data custodians for any external agents such as state contractors, subcontractors or other organizations that will storing the VHCURES data set or derived files.*

|  |
| --- |
| Name and Title of Data Custodian (State Agency) |
| Same as PI |
| OrganizationWebsite |
|  |
| Street Address |
|  |
| City | State | Zip |
|  |  |  |
| Telephone | Email |
|  |  |

|  |
| --- |
| Name and Title of Data Custodian |
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| OrganizationWebsite |
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| Street Address |
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| City | State | Zip |
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| Telephone | Email |
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| --- |
| Name and Title of Data Custodian |
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| OrganizationWebsite |
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| Street Address |
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| City | State | Zip |
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| Telephone | Email |
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### Individual Users

*Identify all individuals within your organization and external agents who will be participating on this project. These individuals may be project managers, analysts, IT professionals, or any other person who may have access to row-level data or aggregate reports prior to the suppression of small n. You must attach a signed individual user affidavit for each of these individual users prior to the receipt of the data after the DUA is approved including any users not identified on this list when this application was submitted.*

|  |  |  |
| --- | --- | --- |
| Name | Organization | Project Role or Title |
| Dr. Kyongsik Yun | HammurabiBerkeley SkyDeck | PI |
| Dr. Daniel Zougbhie | HammurabiBerkeley SkyDeck | Agent |
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## Section 4: Data Procurement and Price

The authorized user will receive the data from the GMCB’s designated data processing vendor for a fee determined by the number of years of data and whether any complex customization is required. The authorized use may contact the vendor in advance to confirm the exact pricing that generally runs about $5,200 for an extract of paid claims data spanning five (5) years. Prices are subject to change.

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 may be fees for custom extracts. Typically, custom extracts are generated to support the data stewardship principle of disclosing the minimum necessary data to support the research purpose. Data users may be authorized to access a secured 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. Fees will be determined on a case-by-case basis. Onpoint Health Data will manage any invoicing for fees.

*The GMCB’s designated vendor for the VHCURES Limited Use 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](http://www.onpointhealthdata.org/)

## Section 5: 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 you in determining whether you are able 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: Dr. Daniel Zoughbie** |
|  |
| **Title/Role in the Project: AU** |
| **If not AU, PI or DC, designated by:** |
| **Email Address:** **s**ameas above |
| **Phone Number: s**ame as above |
| **Organization/Agency Affiliation: same as above** |
| **Street, City, ZIP Address:**  same as above |
|  |

## Section 6: Signatures

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

|  |
| --- |
| **Authorized User Name: Daniel Zoughbie** |
| Signature: | Date: 10-28-22 |

|  |
| --- |
| **Principal Investigator 1 Name** (if different from Authorized User):  **Daniel Zoughbie** |
| Signature: | Date: 10-28-22 |

|  |
| --- |
| **Principal Investigator 2 Name:** |
| Signature: | Date: |

### GMCB Processing Section

**For GMCB Use Only**

Date Application Deemed Complete:

DVHA Application Approval Date:

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: