

CENTER FOR IMPROVING

Data Release Application Limited and Identifiable Extract

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Client Application Revision History

The following reflects the history of changes made to this document during the application process prior to project production. Once in production, any further changes to the application may result in additional cost and production delays.

To be completed by CIVHC staff								
Date	New Version Number	Description of Change(s) CIVHC Change Au						
3/1/2024	V.01	Initial version drafted with client.	Lucía Sanders, Key Account Manager					
4/22/2024	V.02	Updates completed during client meeting.	Lucía Sanders, Key Account Manager					
5/10/2024	V.03	Updates to project schedule, PHI elements, and IRB.	Lucía Sanders, Key Account Manager					
6/27/2024	V.04	Clarified member filter criteria. Updated document versions presented at application review.	Lucía Sanders, Key Account Manager					
Date	V.05	Click or tap here to enter text.	Name, Title					
Date	V.06	Click or tap here to enter text.	Name, Title					
Date	V.07	Click or tap here to enter text.	Name, Title					
Date	V.08	Click or tap here to enter text.	Name, Title					
Date	V.09	Click or tap here to enter text.	Name, Title					
Date	V.10	Click or tap here to enter text.	Name, Title					
Date	V.11	Click or tap here to enter text.	Name, Title					
Date	V.12	Click or tap here to enter text.	Name, Title					
Date	V.13	Click or tap here to enter text.	Name, Title					
Date	V.14	Click or tap here to enter text.	Name, Title					
Date	V.15	Click or tap here to enter text.	Name, Title					

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Data Requestor Details

General Project Details

Project Title:	Equity in Cancer Care: Exploring Emergency Department Diagnosis, Disparities, and Economic Impact in Gastrointestinal Cancers.				
Application Start Date:	3/1/2024				
Requested Project Delivery Date:	1/1/2025				
Client Organization:	Rutgers Cancer Institute of New Jersey				
Client Organization Address:	195 Little Albany Street, New Brunswick, New Jersey, 08901				
To b	e completed by CIVHC staff				
CIVHC Contact:	Lucía Sanders				
Project Number:	24.41				
Condensed Project Title:	Equity Cancer Care				

Project Contacts

Project Contact Name:	Brijesh Rana					
Title:	Research Coordinator					
Email:	bbr26@cinj.rutgers.edu					
Phone Number:	nber: 848-437-0123					
Analytic Contact Name: Dr. Elizabeth Handorf						
Title:	Associate Professor					
Email:	ehandorf@cinj.rutgers.edu					
Phone Number:	Click or tap here to enter text.					
Invoice Contact Name:	Linda Hurley					
Title:	Senior Financial Analyst					
Email:	lh400@cinj.rutgers.edu					
Phone Number:	Click or tap here to enter text.					

Data Release Fee Signatory

Name:	Haejin In
Title:	Associate Professor of Surgery
Email:	hi80@cinj.rutgers.edu

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Data Use Agreement Signatory

Name:	Haejin In
Title:	Associate Professor of Surgery
Email:	hi80@cinj.rutgers.edu



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Project Schedule and Purpose

Proposed Project Start Date ¹ :	1/1/2025
Anticipated Project End Date:	12/31/2030
Proposed Publication or Release Date:	12/31/2031

1. Detail the specific research question(s) you are trying to answer or problem(s) you are trying to solve with this data request. Please list and number the individual questions.

a. Identify multilevel individual and neighborhood predictors of patients who initially present to the ED to obtain care that precedes their GI cancer diagnosis (PreDxED)

b. Evaluate whether preDxEd mediates or moderates socioeconomic and racial and ethnic disparities in GI cancer quality of care.

c. Identify provider and hospital factors associated with quality and timeliness of cancer care for PreDxED patients.

2. Describe your methodology or how you will be using data from the Colorado All Payer Claims Database (CO APCD) to answer your research questions.

Analysis will be conducted using the CO APCD claims data linked with Colorado Central Cancer Registry data. Data linkage between the APCD and cancer registry is necessary to investigate ED-dx as this linkage allows identification of the location of care for every new cancer patient diagnosed, capturing patients of all ages and across most of state's health care system.

We aim to :

Aim 1 – Identify multilevel individual and neighborhood predictors of PreDxED GI cancer diagnoses. Using demographic, clinical, and ZIP code-level social determinants of health and spatial accessibility data from APCD and registries, we will identify individual- and place-based correlates of PreDxED. H1: Socioeconomically and racial/ethnically disadvantaged groups are more likely to be PreDxED.

Aim 2 – Evaluate whether preDxEd mediates or moderates socioeconomic and racial and ethnic disparities in GI cancer quality of care. H2a: ED-dx mediates delays in GI cancer treatment initiation and disparities in receipt of guideline concordant care. H2b: The racial and

¹ After all required documents have been signed and the Data Release Review Committee has approved the project, typical production time is 30-60 days for a Limited or Identifiable Extract. Anticipate a longer production period for projects including a Finder File or creation of a Member Match File.



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socioeconomic disparity in treatment delays and receipt of guideline concordant care varies based on PreDxEd status.

Aim 3 – Identify provider and hospital factors associated with quality and timeliness of cancer care for PreDxED patients. We will link facility-level data from the American Hospital Association on staffing, equipment, and patient volume to PreDxEd patients identified in the APCD-registry linked database. We will assess associations of provider and facility-level factors with concordance to standards of cancer care and delivery of timely care for patients.

3. Explain how this project will benefit Colorado and its residents.²

Our study has great potential to profoundly impact healthcare practices and policies to benefit the population of Colorado. Understanding which populations are at risk of ED-dx, the factors that drive poor outcomes, and having knowledge of resources needed to care for these patients is necessary to improve outcomes and reduce disparities for GI cancer patients and help improve the health and lives of the people living in Colorado through this research project.

4. Describe how your project will improve health care quality, increase health care value, or improve health outcomes for Colorado residents.²

This project aims to improve healthcare quality, increase healthcare value, and enhance health outcomes for Colorado residents, particularly those facing disparities. By identifying predictors of emergency department diagnoses (ED-dx) for Gastrointestinal cancers, the study seeks to enhance detection and address disparities in socioeconomically and racially/ethnically disadvantaged groups across the state of colorado. The exploration of ED-diagnosis as a mediator and moderator of poor cancer care, along with the characterization of healthcare utilization and costs, will provide valuable insights for targeted interventions and resource allocation. The findings are expected to inform evidence-based healthcare practices and policies, contributing to a reduction in GI cancer burden and improved overall health outcomes in Colorado.

5. Health equity is defined as the state in which everyone has a fair and just opportunity to attain their highest level of health. Explain how your project addresses health equity.

This project is designed to foster health equity by investigating disparities in GI cancer diagnosis, care, and outcomes, with a specific emphasis on socioeconomically and racially/ethnically

² It is a statutory requirement for all non-public releases of CO APCD data to benefit Colorado or its residents. Contributions to generalizable knowledge alone are not sufficient to satisfy this requirement.



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disadvantaged populations and also pave the way for a more inclusive and equitable healthcare system for all residents in Colorado.

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Data Matching and Linkage

Finder File

A Finder File is a file you submit to CIVHC with information about a pre-selected cohort for matching to CO APCD data. Ask your CIVHC Contact for more information about this process and requirements for Finder File submission.

Will you provide CIVHC with a Finder File as part of this project?

⊠ No □ Yes

Member Match File

A Member Match File is a file that CIVHC creates on your behalf to send to a registry or other outside entity to create a crosswalk connecting data from the CO APCD to the other entity's data.

Does this project require the creation of a Member Match File?

🗆 No

Yes. Consult with your CIVHC Contact about completing a <u>Member Match File Data Element</u> <u>Selection Form</u>. Answer the following:

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Who will receive the Member Match File?
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Colorado Central Cancer Registry at CDPHE

Control Group

A Control Group is a group of individuals who can be used to compare against the cohort identified in the Finder File.

Will you need to create a Control Group as part of this project?

🛛 No

□ Yes. Consult with your CIVHC Contact about completing a <u>Control Group Data Element</u> <u>Selection Form</u>.

Linkage

Data Linkage is a method of joining data from different sources together to create a new data set.

Will the CO APCD data be linked to another data source?

🗌 No

 \boxtimes Yes. Answer the following:



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What is (are) the other data source(s)?

Colorado Hospital Association hospital discharge and emergency room data, Colorado Central Cancer Registry Data, and other state APCD and Cancer registry data (planned for Arkansas, Utah, and Washington)

Who will perform the data linkage?

Rutgers project team will utilize their analytic resources to perform the linkage with Colorado Central Cancer registry and Colorado Hospital Association data elements.

What identifying data elements will be used to perform the data linkage?

Individual person-level crosswalk ID

What non-CO APCD data elements will appear in the new linked file?

Birth and death certificate data from cancer registry, cancer data from cancer registry, emergency department and hospital discharge data from Colorado Hospital Association



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Data Inclusion Criteria

Make selections in the following sections based on what data you want to have included in this extract. If you will be creating a Control Group, complete this section for your study population and not the Control Group.

Protected Health Information

Indicate which <u>Protected Health Information</u> data elements you require for your project purpose:

	Available for Limited and Identi	fiable extracts:							
	🛛 Member 5-Digit Zip Code	Member <u>Census Tract</u>	Member County						
	Member City	☑ Member Eligibility Date	🗌 Employer Tax ID						
	☑ Member Dates of Service								
	Available for Identifiable extrac	ts only (see also <u>Identifiable Data</u>	<u>u Use Approval</u>):						
	Member Name	□ Member Date of Birth (if rec	questing more than year only)						
	Member Geocoded	Member Geocoded Latitude and Longitude							
	Address								
	Provide detailed justification fo its inclusion meets the Minimum	r the inclusion of all PHI data sele <u>n Necessary Requirement</u> . ³	ected above, and explain how						
	requested are zip code and trea	el data is as limited as possible – atment dates, which are necessar ility dates are needed to examin	y to define key variables for						
Lin	e(s) of Business								

- ⊠ Commercial Payers
- ☑ Health First Colorado (Colorado's Medicaid and CHP+ programs)⁴
- ⊠ Medicare Advantage
- Medicare Fee for Service (FFS)⁵

Year(s) of Data

□ 2012 □ 2013 □ 2014 □	2015 🗌 2016 🖾 201
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³ Limited and Identifiable extracts must adhere to the <u>Minimum Necessary Requirement</u> under the <u>HIPAA Privacy</u>

Rule; only that data required to answer the project purpose can be included in the request.

⁴ Medicaid-only data requests must be approved by the Colorado Department of Health Care Policy and Financing. ⁵ Medicare EES data are not available for all requests and must ge through a separate approach process.

⁵ Medicare FFS data are not available for all requests and must go through a separate approval process.



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\boxtimes	2018	\boxtimes	2019	\boxtimes	2020	\boxtimes	2021	\boxtimes	2022	\times	20236
Claim	Types										
\boxtimes	Inpatient Fa	cility	,	\boxtimes	Outpatient	Faci	lity	\boxtimes	Professiona	ł	
	Pharmacy				Dental						
Financ	ial Detail	by l	ine Item								
\boxtimes	Charged An	nour	nt	\boxtimes	Allowed Am	nour	nt	\boxtimes	Plan Paid Ar	nou	Int
\boxtimes	Plan Pre-Pai	d Aı	nount	\boxtimes	Member Co	рау		\boxtimes	Member De	duc	tible
\boxtimes	Member Co	oinsu	irance	\boxtimes	Total Memb	er l	_iability				

Filter Criteria – Services, Providers, Facilities

If you need data for specific services, providers and/or facilities, specify that filter criteria below (ask your CIVHC Contact about including an additional file with this application for large code lists):

ICD Diagnosis Code(s):
Procedure(s) (list CPT, HCPCS, DRG, ICD, and/or CDT codes):
Please specify here.
Drug(s) (list pharmacy NDC and/or HCPCS codes):
Please specify here.
Facility Type(s):
Facilities (list NPIs and/or Pharmacy IDs):

⁶ This year's data is incomplete. Consult with your CIVHC Contact to find out what data is available at the time of your request.



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Facilities within these geographical areas (list county, zip code, Census Tract, etc.):
Provider Type(s):
Provider(s) (list NPIs):
Providers within these geographical areas (list county, zip code, <u>Census Tract</u> , etc.):
Please specify here.
Specific payers (minimum of five):
Please specify here.
Other claim specification:
Please specify here.

Filter Criteria – Members/Patients

If you need data for specific member/patient groups, specify that filter criteria below (ask your CIVHC Contact about including an additional file with this application for large code lists):

Ages:				
18 years and older				
\boxtimes At the time of service.	□ At year end	□ By another anchor date:		
		Please specify here.		
With these ICD Diagnosis C	ode(s):			
See ICD code list added to DESF. Cancer types being requested include: Esophageal, Stomach, Pancreas, Hepatobiliary, and Colorectal cancers.				
Who have had the following procedure(s) (list CPT, HCPCS, DRG, ICD, and/or CDT codes):				



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Within these geographical areas (list county, zip code, <u>Census Tract</u>, etc., in keeping with your selected <u>Protected Health Information</u>):

Please specify here.

Value-Add Data Elements

Indicate which (if any) of the following value-add options you would like included with this extract:

- Medicare Severity Diagnosis Related Group Codes (MS-DRGs)
- 3M All Patient Refined Diagnosis Related Group Codes (3M APR DRGs)
- Medicare Repricer
- □ Fields from the <u>American Community Survey</u>:

Please specify here.

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Additional Documentation

Data Element Selection Form

The Data Release Application must be accompanied by a completed Data Element Selection Form to be reviewed internally and by the Data Release Review Committee. Ask your CIVHC Contact for more information about completing this form.

By checking this box, the Client Organization confirms that the Data Element Selection Form has been completed.

□ By checking this box, the Client Organization confirms that a separate <u>Member Match File</u> <u>Data Element Selection Form</u> has been completed, if applicable.

□ By checking this box, the Client Organization confirms that a separate <u>Control Group Data</u> <u>Element Selection Form</u> has been completed, if applicable.

Identifiable Data Use Approval

If you are requesting <u>Identifiable</u> information, approval from an <u>Institutional Review Board</u> (<u>IRB</u>) or a <u>Privacy Board</u> is required before such data can be released.

□ Not applicable; the Client Organization is requesting a Limited Extract.

Approval Type

- 🛛 IRB approval
- □ Privacy Board approval

State of Approval

- Approval request not yet submitted. Anticipated submission date: 6/15/2024
- Approval request submitted and under review.
 Anticipated project approval date: Date
- □ Approval already received.

Approval Documentation

□ By checking this box, the Client Organization confirms that the IRB or Privacy Board application and approval documents have been provided to CIVHC.





Data Management Plan

An organization requesting CO APCD data must submit an organizational Data Management Plan to CIVHC outlining the organization's data security and data management policies and procedures to safeguard the data. This Data Management Plan must be approved by CIVHC prior to any data release.

 $\hfill\square$ Submitted to CIVHC on Date

 $\hfill\square$ Approved by CIVHC on Date

Client Acknowledgements and Signatures

Change Agent Index

CIVHC can publicly share the Client Organization's name in its Change Agent Index.

🛛 Yes 🗌 No

Report or Product Distribution

If your project results in the production of a report for public distribution in any format (print, electronic, lecture, slides, etc.), including peer-reviewed publication, it must be submitted to CIVHC for review prior to public release. CIVHC will assess compliance with <u>CMS cell suppression rules</u>, risk of inferential identification, CIVHC and CO APCD citations, and consistency with the purpose and methodology described in this Data Release Application. CIVHC will not assess the accuracy of the study results or attempt to recreate results.

This requirement is further defined in the Data Use Agreement. Failure to pursue and obtain CIVHC approval prior to publication will be a violation of the Data Use Agreement and may put the organization's future access to data from the CO APCD at risk.

By checking this box, the Client Organization acknowledges this requirement.





Data Destruction Period

All data must be destroyed within 30 days of the project end date. If your project end date changes from this application, please reach out to your CIVHC Contact for a project extension request form.

 \boxtimes By checking this box, the Client Organization acknowledges that CIVHC's <u>Data Destruction</u> <u>Certificate</u>⁷ must be completed and returned to <u>DataCompliance@CIVHC.org</u> by 1/30/2031 based on the <u>Anticipated Project End Date</u>.

Data Users

List any individuals that will be working with the data. The Data Use Agreement must be updated through your CIVHC Contact every time individuals are granted access to the data during the course of the project.

Name	Role	Organization
Haejin In, MD, MPH, MBA, FACS, FSSO	Principal Investigator	Rutgers Cancer Institute of New Jersey
Hari Iyer, ScD, MPH	Co-Investigator	Rutgers Cancer Institute of New Jersey
Elizabeth Handorf, PhD	Co-Investigator	Rutgers Cancer Institute of New Jersey
Antoinette Stroup, PhD	Co-Investigator	Rutgers Cancer Institute of New Jersey
Sara Heinert, PhD	Co-Investigator	Rutgers Cancer Institute of New Jersey
Brijesh Rana, BDS, MS	Research Coordinator	Rutgers Cancer Institute of New Jersey
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Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

⁷ Available on the <u>Data Release Application and Documents</u> page of CIVHC's website under *Privacy, Security, and Regulatory Information*.



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Data Release Application Version Approvals

Checkpoint 1: Preparation for CIVHC's internal Application Review Meeting

The Client Organization has reviewed and confirms that V.03 of this Data Release Application represents the correct details to meet the project objectives.

CIVHC Sign-Off		Receiving Organization Sign-Off	
Initials:	Click or tap here to enter text.	Initials:	Click or tap here to enter text.
Name:	Click or tap here to enter text.	Name:	Click or tap here to enter text.
Title:	Click or tap here to enter text.	Title:	Click or tap here to enter text.
Date:	Date	Date:	Date

Checkpoint 2: Preparation for presentation to the Data Release Review Committee

The Client Organization has reviewed and confirms that V.04 of this Data Release Application represents the correct details to meet the project objectives.

CIVHC Sign-Off		Receiving Organization Sign-Off	
Initials:	Click or tap here to enter text.	Initials:	Click or tap here to enter text.
Name:	Click or tap here to enter text.	Name:	Click or tap here to enter text.
Title:	Click or tap here to enter text.	Title:	Click or tap here to enter text.
Date:	Date	Date:	Date

Checkpoint 3: Final approval to begin project production

The Client Organization has reviewed and confirms that V.00 of this Data Release Application represents the correct details to meet the project objectives.

CIVHC Sign-Off		Receiving Organization Sign-Off	
Signature:		Signature:	
Name:	Click or tap here to enter text.	Name:	Click or tap here to enter text.
Title:	Click or tap here to enter text.	Title:	Click or tap here to enter text.
Date:	Date	Date:	Date



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Data Element Selection Form Version Approvals

Checkpoint 1: Preparation for CIVHC's internal Application Review Meeting

The Client Organization has reviewed and confirms that V.03 of this Data Release Application represents the correct details to meet the project objectives.

CIVHC Sign-Off		Receiving Organization Sign-Off	
Initials:	Click or tap here to enter text.	Initials:	Click or tap here to enter text.
Name:	Click or tap here to enter text.	Name:	Click or tap here to enter text.
Title:	Click or tap here to enter text.	Title:	Click or tap here to enter text.
Date:	Date	Date:	Date

Checkpoint 2: Preparation for presentation to the Data Release Review Committee

The Client Organization has reviewed and confirms that V.03 of this Data Release Application represents the correct details to meet the project objectives.

CIVHC Sign-Off		Receiving Organization Sign-Off	
Initials:	Click or tap here to enter text.	Initials:	Click or tap here to enter text.
Name:	Click or tap here to enter text.	Name:	Click or tap here to enter text.
Title:	Click or tap here to enter text.	Title:	Click or tap here to enter text.
Date:	Date	Date:	Date

Checkpoint 3: Final approval to begin production

The Client Organization has reviewed and confirms that V.00 of this Data Release Application represents the correct details to meet the project objectives.

CIVHC Sign-Off		Receiving Organization Sign-Off	
Signature:		Signature:	
Name:	Click or tap here to enter text.	Name:	Click or tap here to enter text.
Title:	Click or tap here to enter text.	Title:	Click or tap here to enter text.
Date:	Date	Date:	Date