



# 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 Author		
1/23/2024	V.01	Initial version drafted with client.	Lucía Sanders, Key Account Manager		
1/30/2024	V.02	Minor updates after internal CSSI review.	Lucía Sanders, Key Account Manager		
2/19/2024	V.03	Updated DMP approval. Collected sign off for DRRC.	Lucía Sanders, Key Account Manager		
3/8/2024	V.04	Added Professional claims and noted linkage to ACS data.	Lucía Sanders, Key Account Manager		
3/14/2024	V.05	Updated invoice contact.	Lucía Sanders, Key Account Manager		
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:	What is emergent enough? Quantifying life-threatening pregnancy complications for a post-Dobbs world
Application Start Date:	1/12/2024
Requested Project Delivery Date:	4/15/2024
Client Organization:	University of Colorado School of Medicine, Division of Complex Family Planning
Client Organization Address:	8111 E Lowry Blvd, Ste 220, Denver, CO 80230
To k	e completed by CIVHC staff
CIVHC Contact:	Lucía Sanders
Project Number:	24.26
Condensed Project Title:	Quantifying Pregnancy Complications

### **Project Contacts**

Project Contact Name:	Nancy Fang, MD MS		
Title:	Assistant Professor		
Email:	Nancy.fang@cuanschutz.edu		
Phone Number:	508-733-6187		
Analytic Contact Name:	Nancy Fang, MD MS		
Title:	Assistant Professor		
Email:	Nancy.fang@cuanschutz.edu		
Phone Number:	508-733-6187		
Invoice Contact Name:	Majik Abidzhanova		
Title:	Business Support Director		
Email:	majik.abidzhanova@cuanschutz.edu		
Phone Number:	N/A		

### Data Release Fee Signatory

Name:	Chrissy Alexander
Title:	Senior Purchasing Agent

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Email: chrissy.alexander@cu.edu

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## Data Use Agreement Signatory

Name:	Alison Lakin
Title:	Vice Chancellor for Regulatory Compliance
Email:	Alison.Lakin@cuanschutz.edu

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### Project Schedule and Purpose

Proposed Project Start Date <sup>1</sup> :	1/15/2024
Anticipated Project End Date:	1/15/2029
Proposed Publication or Release Date:	1/15/2027

- 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.
  - I. What is the incidence of pregnant people in Colorado that have pre-existing chronic health conditions that increase their risk of morbidity and mortality?
  - 2. What is the incidence of pregnant people in Colorado that have pregnancy complications?
  - 3. What is the incidence of pregnant people in Colorado who receive an abortion secondary to threat to maternal health?
  - 4. Does geographic location affect pregnancy outcomes?
  - 5. How do these results compare to another state (Virginia)? What are the possible differences in health policy that contribute to these findings found between the two states?
- 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.

Using codes that identify diagnoses, procedures and surgeries (i.e., International Classification of Diseases (ICD) and Current Procedural Terminology (CPT) as well as demographic information about the patients, we can use this dataset to identify pregnant people and common conditions that threaten maternal health.

We will characterize pregnancy outcomes (live birth, miscarriage, ectopic pregnancy, stillbirth, induced abortion) as well as any sequelae that may be related to underlying conditions. We will use findings on the prevalence of underlying health conditions to model the population impact of legal changes to abortion access.

We will also conduct a spatial analyses using ArcGis. We will generate maps of census tracts related to maternal outcomes and access to hospitals with labor and delivery.

We are requesting all lines of business in this dataset, including Medicare, due to

<sup>&</sup>lt;sup>1</sup> 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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Medicare's coverage of patients under 65 for those with a confirmed medical disability. Many patients who are of reproductive age and medical disability have increased risk to health during pregnancy.

We are also requesting pharmacy claims for medications as there are certain medications that are teratogenic during pregnancy or that are associated with medical conditions that place a person at risk of severe medical morbidity or mortality during pregnancy.

3. Explain how this project will benefit Colorado and its residents.<sup>2</sup>

There is a maternal morbidity and mortality crisis in the United States and affects our residents in Colorado. This project aims to quantify the number of Colorado residents who are living with health conditions that are dangerous in pregnancy and describe their pregnancy outcomes. This baseline information will be important to establish as Colorado continues to be a leader in supporting efforts in accessing reproductive healthcare and improving maternal, fetal, and neonatal outcomes. In collaboration with my colleagues at Duke University, we plan to use this data to create a model that can predict the impacts of supportive or unsupportive health policy related to reproductive health.

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

By characterizing people with health conditions that affect the health of their pregnancy and comparing them to other states (including Virginia), our team will be able to identify risk markers associated with different pregnancy outcomes. While our team understands that maternal morbidity and mortality involves a complex interplay of socioeconomic and structural factors that may not be captured in the claims database, this project can help identify specific populations that may benefit from further support or services due to inequities revealed by our analysis.

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.

Our team is especially interested in health disparities. Already, non-Hispanic Black women have three times greater maternal mortality than other groups. Abortion bans are projected to worsen health disparities because of the racial and ethnic demographics in states banning abortion, economic limitations on ability to travel out-of-state to seek abortion care, and disparate access to health care in general. Colorado remains a state that has protected access to abortion while Virginia has not. Our analysis aims to decipher if differences in health policy can affect maternal health outcomes.

<sup>&</sup>lt;sup>2</sup> 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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# 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 othe 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?
<ul> <li>No</li> <li>☐ Yes. Consult with your CIVHC Contact about completing a Member Match File Data Element</li> <li>Selection Form. Answer the following:</li> </ul>
Who will receive the Member Match File?
Please specify here.
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?
<ul> <li>☑ No</li> <li>☐ Yes. Consult with your CIVHC Contact about completing a <u>Control Group Data Element</u></li> <li><u>Selection Form</u>.</li> </ul>
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?
Will the CO APCD data be linked to another data source?  ☐ No ☐ Yes. Answer the following:

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

American Community Survey (ACS)

Who will perform the data linkage?

Anschutz Research Team

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

Census tract

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

Social Vulnerability Index (SVI) and the Area Deprivation Index (ADI)

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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 Protected Health Information data elements you require for your project purpose:

Available for Limited and Identifiable extracts:					
☑ Member <u>Census Tract</u>	☐ Member County				
☐ Member Eligibility Date ☐ Employer Tax ID					
only (see also <u>Identifiable Data</u>	Use Approval):				
☐ Member Date of Birth (if red	questing more than year only)				
☐ Member Geocoded Latitude and Longitude					
Provide detailed justification for the inclusion of all PHI data selected above, and explain how its inclusion meets the Minimum Necessary Requirement. <sup>3</sup>					
Including the 5 digit zip code, census tract and member dates of service will be beneficial in our analyses for several reasons:					
Geographic Analysis: Member zip codes and census tracts provide geographical information that can be used for regional trends, demographic profiling, and resource allocation. Understanding where services are being utilized can help identify areas for resource allocation. Service Utilization Patterns: Dates of service enable analysis of when services are being utilized by members. This information can help in identifying patterns such as seasonal variations, or trends over time.					
Quality of Care Evaluation: Disparities in service utilization across different zip codes may					
indicate areas where additional resources or interventions are needed to ensure equitable					
access to care.					
r i i	Member Census Tract  Member Eligibility Date  Only (see also Identifiable Data  Member Date of Birth (if rec  Member Geocoded Latitude  Member Geoco				

# Line(s) of Business

<sup>&</sup>lt;sup>3</sup> Limited and Identifiable extracts must adhere to the Minimum Necessary Requirement under the HIPAA Privacy Rule; only that data required to answer the project purpose can be included in the request.

<sup>&</sup>lt;sup>4</sup> Medicaid-only data requests must be approved by the Colorado Department of Health Care Policy and Financing.

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	<ul> <li>✓ Medicare Advantage</li> <li>✓ Medicare Fee for Service (FFS)<sup>5</sup></li> </ul>									
Year	Year(s) of Data									
	□ 2012	□ 2013		2014		2015		2016		2017
	⊠ 2018	⊠ 2019	$\boxtimes$	2020		2021		2022		20236
Clai	m Types									
		cility	$\boxtimes$				I			
				Dental						
Fina	ncial Detail	by Line Item								
	☐ Charged Ar	mount		Allowed An	nour	nt	☐ Plan Paid Amount			
	☐ Plan Pre-Pai	id Amount		Member Co	рау		☐ Member Deductible			
	☐ Member Co	oinsurance		Total Memb	oer L	iability				
Filte	er Criteria – S	Services, Prov	/ide	ers, Faciliti	es					
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):									
	Please specify here.									
	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):										
_	Please specify here.									
	Facilities (list N	PIs and/or Pharn	nacy	/ IDs):						

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<sup>&</sup>lt;sup>5</sup> Medicare FFS data are not available for all requests and must go through a separate approval process.

<sup>&</sup>lt;sup>6</sup> This year's data is incomplete. Consult with your CIVHC Contact to find out what data is available at the time of your request.





Please specify here.
Facilities within these geographical areas (list county, zip code, Census Tract, etc.):
Please specify here.
Provider Type(s):
Please specify here.
Provider(s) (list NPIs):
Please specify here.
Providers within these geographical areas (list county, zip code, Census Tract, 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:					
Younger than 55					
$\square$ At the time of service.					
		Please specify here.			
With these ICD Diagnosis C	ode(s):				
Please see "ICD10 codes-Filter" tab in the CIVHC Data Request Form					
Who have had the following procedure(s) (list CPT, HCPCS, DRG, ICD, and/or CDT codes):					
Please specify here.					
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.					

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varac / taa b	ande Mad Bata Elements							
Indicate which extract:	ndicate which (if any) of the following value-add options you would like included with this extract:							
☐ 3M All ☐ Medica	are Severity Diagnosis Related Group Codes (MS-DRGs)  Patient Refined Diagnosis Related Group Codes (3M APR DRGs)  are Repricer  from the American Community Survey:							
Ple	ease 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.

oxtimes By checking this box, the Client Organization confirms that the Data Element Selection Formhas been completed.	n
☐ By checking this box, the Client Organization confirms that a separate Member Match File Data Element Selection Form has been completed, if applicable.	
☐ By checking this box, the Client Organization confirms that a separate Control Group Data Element Selection Form 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> (IRB) or a <u>Privacy Board</u> is required before such data can be released.	
$\ \square$ Not applicable; the Client Organization is requesting a Limited Extract.	
Approval Type	
<ul><li>☑ IRB approval</li><li>☐ Privacy Board approval</li></ul>	
State of Approval	
☐ Approval request not yet submitted.  Anticipated submission date: Date	
☐ 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.	

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#### 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.

	Submitted to CIVHC on Date
$\boxtimes$	Approved by CIVHC on 2/19/2024

### Client Acknowledgements and Signatures

Change Agent Index	(
CIVHC can publicly sha	re the Client Organization's name in its <a href="Change Agent Index">Change Agent Index</a> .
⊠ 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 CMS cell suppression rules, 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.

⊠ By checking this box, the Client Organization acknowledges that CIVHC's <u>Data Destruction</u> <u>Certificate</u><sup>7</sup> must be completed and returned to <u>DataCompliance@CIVHC.org</u> by 2/15/2029 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
Nancy Fang, MD MS	PI	School of Medicine, CU Anschutz
Jeanelle Sheeder, PhD, MSPH	Co-Investigator	School of Medicine, CU Anschutz
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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.
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<sup>&</sup>lt;sup>7</sup> 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.02 of this Data Release Application represents the correct details to meet the project objectives.

CIVHC Sig	n-Off	Receiving Organization Sign-Off		
Initials:	LS	Initials:	NF	
Name:	Lucía Sanders	Name:	Nancy Fang	
Title:	Key Account Manager	Title:	Assistant Professor	
Date:	1/30/2024	Date:	1/30/2024	

#### 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 Sig	n-Off	Receiving Organization Sign-Off		
Initials:	LS	Initials:	NF	
Name:	Lucía Sanders	Name:	Nancy Fang	
Title:	Key Account Manager	Title:	Assistant Professor	
Date:	2/19/2024	Date:	2/20/2024	

#### Checkpoint 3: Final approval to begin project production

The Client Organization has reviewed and confirms that V.05 of this Data Release Application represents the correct details to meet the project objectives.

CIVHC Sign-0	Off	Receiving Organization Sign-Off		
Signature:	Docusigned by: Luc'la Sanders AB52282502CE462	Signature:	DocuSigned by:  AB3C8FC4A7A740D	
Name:	Lucía Sanders	Name:	Nancy Fang	
Title:	Key Account Manager	Title:	Assistant Professor	
Date:	Date 3/14/2024	Date:	Date 3/14/2024	

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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.02 of this Data Release Application represents the correct details to meet the project objectives.

CIVHC Sig	n-Off	Receiving Organization Sign-Off		
Initials:	LS	Initials:	NF	
Name:	Lucía Sanders	Name:	Nancy Fang	
Title:	Key Account Manager	Title:	Assistant Professor	
Date:	1/30/2024	Date:	1/30/2024	

#### 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 Sig	n-Off	Receiving Organization Sign-Off		
Initials:	LS	Initials:	NF	
Name:	Lucía Sanders	Name:	Nancy Fang	
Title:	Key Account Manager	Title:	Assistant Professor	
Date:	2/19/2024	Date:	2/20/2024	

#### Checkpoint 3: Final approval to begin production

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-C	Off	Receiving Organization Sign-Off		
Signature:	Docusigned by: Luc'la Sanders AB52282502CE462	Signature:	DocuSigned by:  AB3C8FC4A7A740D	
Name:	Lucía Sanders	Name:	Nancy Fang	
Title:	Key Account Manager	Title:	Assistant Professor	
Date:	Date 3/14/2024	Date:	Date 3/14/2024	