

Colorado All Payer Claims Database Data Release Application

Thank you for your interest in obtaining data from the CO APCD. As you fill out this application, please let us know if you have any questions or concerns by reaching out to ColoradoAPCD@civhc.org. We are here to help!

Also, please be aware that if you are requesting Protected Health Information (PHI), your request requires a recommendation for approval by the Data Release Review Committee (DRRC). Data elements that are considered PHI under HIPAA are indicated below. If PHI is requested, a CIVHC Account Executive will help you successfully complete an application and navigate the DRRC process.

Please use this application to submit information regarding your request for data from the Colorado All Payer Claims Database (CO APCD). This information will help the Center for Improving Value in Health Care (CIVHC), the Administrator of the CO APCD, answer any questions you have regarding your data request and assist us in helping you complete the data application form.

Note: Please reference the CO APCD Data Elements Request Form found at <http://www.civhc.org/get-data/data-release/> when completing this form.

Introduction: Section 10 CCR 2505-5-1.200.5 describes how the CO APCD Administrator addresses Requests for Data and Reports:

1.200.5.A. A state agency or private entity engaged in efforts to improve health care or public health outcomes for Colorado residents may request a specialized report from the CO APCD by submitting to the administrator a written request detailing the purpose of the project, the methodology, the qualifications of the research entity, and by executing a Data Use Agreement (DUA), to comply with the requirements of HIPAA.

1.200.5. B. A data release review committee shall review the request and advise the administrator on whether release of the data is consistent with the statutory purpose of the CO APCD, will contribute to efforts to improve health care for Colorado residents, and complies with the requirements of HIPAA. The administrator shall include a representative of a physician organization, hospital organization, non-physician provider organization and a payer organization on the data release review committee.

This Data Release Application serves as the written request for information noted in section 1.200.5.A.

PART ONE

Project Information	
Project Title:	21.85 SEARCH for Diabetes in Children and Young Adults 0-45 years (SEARCH-DiCAYA) Diabetes Surveillance Study
Date:	March 10, 2021, updated 5/7/21
Organization Requesting Data:	University of Colorado, Anschutz Medical Campus
Contact Person:	Anna Bellatorre
Title:	Research Associate
E-mail:	anna.bellatorre@cuanschutz.edu
Phone Number:	303-724-7704
Person Responsible for the Project (if different than above):	Tessa Crume
Title:	Associate Professor
E-mail:	Tessa.crume@cuanschutz.edu
Phone Number:	303-724-4452

Project Purpose:

Project questions to be discussed with client representative:

- Please describe your project and project goals/objectives.

We propose to ascertain the annual prevalence and incidence of diabetes among youth <18 years old and young adults aged 18-45 years in the state of Colorado for the years 2017-2024 by aggregating case-finding data from three major data sources: 1) the well- established SEARCH network of endocrinology clinics, community clinics and hospital networks throughout Colorado; 2) the Colorado All Payers Claims Database; and 3) the University of Colorado Health System data warehouse (Health Data Compass). Our integrated surveillance approach will utilize algorithms to identify diabetes cases, distinguish diabetes type and estimate diagnosis date. Incremental record linkage will minimize missing data on key surveillance variables (i.e., race/ethnicity, date of diabetes diagnoses, diabetes type) and improve data quality by aggregating encounter information across data sources.

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

Aim 1: PREVALENCE – Starting with year 2017 and continuing through year 2024, to ascertain prevalent diabetes cases among youth <18 years of age and adults 18-45 years of age on a yearly basis from an integrated surveillance system using algorithms that distinguish diabetes type.

Research question 1.1: What are the yearly state-level age-, sex- and race/ethnicity-specific prevalence estimates of T1D and T2D among youth and young adults?

Research question 1.2: Using prevalence data from SEARCH-Colorado, what are the long-term temporal trends in the prevalence of T1D and T2D and do they vary by race/ethnicity, age, and sex?

Aim 2: INCIDENCE – Starting with year 2017 and continuing through year 2024, to ascertain newly diagnosed diabetes among youth <18 years of age and young adults 18-45 years of age on a yearly basis from an integrated surveillance system using algorithms that estimate date of onset and distinguish diabetes type.

Research question 2.1: What are the yearly state-level age-, sex- and race/ethnicity-specific incidence estimates of T1D and T2D among youth and young adults?

Research question 2.2: Using incidence data from SEARCH-Colorado, what are the long-term temporal trends in the incidence of T1D and T2D and do they vary by race/ethnicity, age and sex?

Research question 2.3: What is the prevalence of diabetic ketoacidosis (DKA) at the time of diagnosis in youth and young adults with T1D and T2D? Using data from SEARCH-Colorado, what are the long-term temporal trends in prevalence of DKA at diagnosis with T1D and T2D?

Aim 3: EVALUATE PUBLIC HEALTH SURVEILLANCE METHOD – To evaluate the strengths and challenges of our integrated surveillance approach to determine the burden of diabetes among youth <18 years of age and young adults 18-45 years of age by ascertaining validity, completeness and representativeness of case ascertainment methods.

Research question 3.1: What is the sensitivity, specificity and positive predictive value of the surveillance approach, overall and by diabetes type in a random sample of T1 and T2 cases?

Research question 3.2: What are the capture-recapture adjusted prevalence and incidence estimates of T1 and T2 diabetes while accounting for the potential bias introduced by less than complete case ascertainment?

- **How will this project benefit Colorado or Colorado residents? (this is a statutory requirement for all non-public releases of CO APCD data)**

Increasing trends in the incidence and prevalence of diabetes among youth and young adults, particularly among various racial and ethnic subpopulations, necessitate an efficient, timely, accurate surveillance system that produce consistent estimates over time that will inform the U.S. health care and public health system, specifically in Colorado, to effectively plan and care for youth with diabetes.

- **Please answer all applicable questions below (Note that your project must meet one or more of the Triple Aim criteria below to generate a benefit for Colorado):**
 - If applicable, how will your project support lowering health care costs?
 - If applicable, how will your project help improve the health of Coloradans?
 - If applicable, how will your project improve the quality of care or patient experience?

Results from this study will provide valuable estimates on the incidence and prevalence of T1D and T2D among children, adolescents, and young adults in Colorado. These estimates will help Colorado, the Western Census Region, and the U.S. implement healthcare planning measures to reach disproportionately impacted sub-populations with diabetes prevention clinical and public health programs as well as tertiary prevention programs to prevent diabetes complications which may ultimately reduce the cost of diabetes care and the financial burden associated with long-term diabetes complications. Timely, accurate estimates of diabetes among youth and young adults is necessary to develop targeted programs that can be translated into primary care settings, daycares, schools, healthcare facilities and community-based facilities (e.g. parks and recreation centers).

- Do you need a claims data set or would you like a custom report generated by CIVHC that addresses the specific questions/problems your project seeks to address?

We need a claims dataset with individual-level information.

- Do you need Protected Health Information (PHI)?

Yes.

- Do you need patient-specific dates (e.g., dates of service or DOB) or 5 digit zip code. If so, this is a request for a **Limited Data Set**.

Yes.

- Do you need direct patient identifiers such as name, address, or city? If so, this is a request for an **Identifiable Data Set** (requires IRB approval).

Yes. Our approval letter from our IRB and HIPAA waiver approval letter are attached.

- If you do not require any PHI, please only complete PART ONE of the application.

Please note: your CIVHC representative will work with you to complete **Addendum I – Analyst Supplement** to address data warehouse specific questions.

If you are requesting a Custom Report with analytics to be provided by CIVHC; please stop here and submit the information above to your CIVHC representative.

PART TWO

I. **Type of CO APCD Analytic Data Set Requested**

Please select the type of data set that you are requesting by checking one of the boxes below (**select only ONE option**). Details on each type of CO APCD data set can be found in *The CO APCD Companion Instruction Guide* (available from your CIVHC representative):

Types of Analytic Data Sets (Please select ONE below)

For users interested in a wide range of data to analyze on their own.

- ☐ De-Identified Data Set
- ☐ Limited Data Set*
- ☒ Identified Data Set *

*These types of data requests include Protected Health Information (PHI). Under HIPAA, PHI may only be released in limited circumstances for public health, health care operations, and research purposes under the terms of a HIPAA compliant data use agreement (DUA).

2. **Requested Data Elements – Limited and Fully Identifiable Data Sets**

The CO APCD is committed to protecting the privacy and security of Colorado's health care claims data. The CO APCD will limit the use of the data to purposes permitted under applicable laws, including APCD Statute/Rule and HIPAA/HITECH, to information reasonably necessary to accomplish the project purpose as described in this Application.

Data Element Selection and Justification

If you have not already done so, please use the Data Element Dictionary (DED) to identify the specific data elements that are required for this project. In keeping with the minimum necessary standard established under HIPAA, CO APCD policy is to release only those data elements that are required to complete your project.

Type of Data	Justification for Elements on the DED
Names	Needed solely for de-duplication of cases. Will be stripped from dataset before inclusion in data surveillance repository.
Street Address	Needed solely for de-duplication of cases. Will be stripped from dataset before inclusion in data surveillance repository.
City	Needed solely for de-duplication of cases. Will be stripped from dataset before inclusion in data surveillance repository.
Zip Code	Needed solely for de-duplication of cases. Will be stripped from dataset before inclusion in data surveillance repository.
Health Plan Beneficiary Numbers	Not needed.
Dates (including Day and Month detail.) Specify which date fields are needed and why.	Encounter Dates and date of birth: Needed for de-duplication of cases and encounters and age classification. Will be stripped from dataset before inclusion in data surveillance repository.
Provider Identifying Information	Not needed. Though we do need provider type/specialty care setting.

A. Counts, Totals and other Summary Statistics

The CO APCD seeks to provide aggregated summary data whenever possible. Applicants are encouraged to request counts, totals, rates and other summary values whenever such information can reasonably accomplish the purpose of the project (add rows to the table below if necessary). The CO APCD supports the federal CMS minimum cell size suppression policy that requires any cell in any report or data table, printed or electronic, with less than eleven records or observations to be replaced by “Less than eleven” or similar text. You must also apply complementary cell suppression techniques to ensure that cells with fewer than eleven records cannot be identified by manipulating data in adjacent rows and columns.

Field Number and Name	Requested Count or Sum
	<i>[add rows as needed]</i>

B. Linkages to Other Data Sets

The CO APCD seeks to ensure that data cannot be re-identified if it is linked to or combined with information obtained from other sources. If this project requires claims line level detail or includes linkages to other databases, or if CO APCD data will be combined with other information, provide a justification for each proposed linkage. Be sure to describe how this will contribute to achieving the project purpose, including whether the project can be completed without this linkage, and the steps you will take to prevent the identification of individual patients:

The goal of our project is to conduct diabetes surveillance across the entire state of Colorado which compels us to request data from multiple healthcare systems to link and de-duplicate across datasets. Our current data partners who will provide encounter-level data to be linked and de-duplicated are: Health data COMPASS at the University of Colorado, Denver Health and Hospital Authority (DHHA), Children's Hospital Colorado (CHCO), SCL Health, Centura Health, Valley Wide Health System, St. Mary's Grand Junction, and Boulder Community Hospital. The linkage, de-duplication, and cleaning of the data obtained from the various data sources will be conducted in a temporary cleaning database. Once the datasets are linked, de-duplicated and cleaned then the data will be stripped of PHI (18 HIPAA identifiers), assigned a new unique study ID and moved into the final diabetes surveillance data repository. This process is described below.

The Colorado School of Public Health will house the complete dataset with full PHI received from the data sources in a password-protected temporary database housed on a Health Data Compass Eureka instance. Eureka is a Google Cloud Platform-based analytic environment that is preconfigured to meet the HIPAA security and compliance standards of the University of Colorado Denver. The temporary database will be used to link, de-duplicate and clean data on cases identified across the various data sources. After the data cleaning process is complete, a new randomly generated unique study ID number will be assigned which refers to both the study record and the data source. After the unique study ID is generated, all PHI will then be stripped away from the primary dataset for storage and the PHI-ID link files will be maintained in a separate password-protected folder on the Eureka instance. The PHI-ID link files will only be accessed for the purpose of record linkage. The de-identified dataset (using the HIPAA definition of a de-identified dataset) will then be transferred to the data repository and the PHI-ID link data will be maintained separately.

The diabetes data repository will only include de-identified encounter level data on cases identified in our primary data sources. The data repository will contain the minimum data necessary for the project needs. The data repository will be stored on a comprehensive password-protected HIPAA-compliant database on a secure internal server. Access will be restricted to the study team.

Will you link the CO APCD data to another data source?

- ☐ No.
- ☒ Yes. If yes, please answer the following questions.
- Which CO APCD identifying data elements will be used to perform the linkage?
First name, last name, middle initial, suffix, date of birth, gender, social security number (if available), home phone, and address.

- Once the linkage is made, what non-CO APCD data elements will appear in the new linked file?

Demographics, encounter, diagnosis, procedures, vitals, lab results, prescribing, and death information from our other data sources. Our other data sources include Health data COMPASS at the University of Colorado, Denver Health and Hospital Authority (DHHA), Children's Hospital Colorado (CHCO), SCL Health, Centura Health, Valley Wide Health System, St. Mary's Grand Junction, and Boulder Community Hospital

- Have all necessary approvals been obtained to receive and link with the other data files (e.g., IRB or Privacy Board approval)?
 - ☒ Yes, if so please provide copy
 - ☐ In progress, anticipated approval date: _____
 - ☐ No or N/A, reason: _____

C. Distribution of the Report or Product: **Prior Review by the CO APCD Administrator**

If you are producing a report for publication in any medium (print, electronic, lecture, slides, etc.) the CO APCD Administrator must review the report prior to public release. The CO APCD Administrator will review the report for compliance with CMS cell suppression rules; risk of inferential identification; and consistency with the purpose and methodology described in this Application.

- Please describe your audience and how to you will make your project publicly available?

We plan to disseminate the results from our project through manuscript publications in scientific journals and presentations given at state and national meetings. We will submit any material for publication in any medium through the CO APCD Administrator for approval prior to publication. We can also provide summary tables and reports to be posted on the CO APCD website.

- If the report is not to be made publicly available, then briefly describe how the information derived from this data will be used and by whom:

Organization/Company Name:	Centers for Disease Control and Prevention
Contact Person:	Ferrinnia Augustus-High
Title:	CDC Grants Management Specialist
Address:	
Telephone Number:	
E-mail Address:	wef9@cdc.gov
Role or responsibility in this project	CDC Grants Management Specialist
Organization/Company Name:	NYU Long Island School of Medicine

Contact Person:	Lorna Thorpe / Jasmin Divers
Title:	Professor / Professor
Address:	180 Madison Ave, NY, NY 10016 / 101 Mineola Boulevard, Mineola, NY 11501
Telephone Number:	646-501-3600 / 516-663-4966
E-mail Address:	Lorna.thorpe@nyulangone.org / jasmin.divers@nyulangone.org
Role or responsibility in this project	Coordinating Center MPIs

Other Organizations: Do you intend to engage third parties who will have access to the data requested as part of this project? If so, list the organizations below, describe their role(s); and explain why they will be granted access to the requested data.

In addition to disseminating the results of the study, we may transmit a de-identified surveillance dataset to the Center for Disease Control and Prevention (who funded the project) or the project's Coordinating Center at New York University (NYU). They will use the de-identified dataset to produce national prevalence estimates of diabetes among youth, adolescents, and young adults.

Project Schedule:

Proposed Project Start Date:	May 7, 2021
Project End Date:	September 29, 2025
Proposed Publication or Release Date:	September 29, 2025
End of Date Retention Period:	September 29, 2026

D. Frequency

Data in the CO APCD Warehouse is refreshed every other month and data products can be provided on a one time basis or under a subscription model (e.g., quarterly, bi-annually or annually). Please select frequency below.

☒ One Time We plan to ask for data 2 times in our 5-year funding period.

OR

Subscription (Please select subscription model below)

- ☐ Quarterly
- ☐ Bi-annually
- ☐ Annually

E. **Project Reporting**

CIVHC highlights projects and data analysis on the public website: www.civhc.org/change-agents. This display of CO APCD projects provides future data requesters with ideas of how they can structure their analysis, and allows CIVHC's stakeholders to see how CO APCD data recipients are working to accomplish the Triple Aim for Colorado. Data recipients have the option of choosing whether to be identified or to not be identified.

- ☒ Yes, it is okay for CIVHC to identify my organization
- ☐ No, I do NOT wish for CIVHC to identify my organization

PART THREE

DATA MANAGEMENT PLAN (Not applicable for Custom Report Requests)

I. **Organizational Capacity**

As an Attachment, please provide copies of the Data Privacy and Security Policies and Procedures for the Requesting Organization as well as those of any third parties that will have access to the requested CO APCD data.

- Has the Requesting Organization or any member of the project team ever been involved with a project that experienced a data security incident? If so, describe the incident, the response procedures that were followed and any subsequent changes in procedures, processes or protocols to mitigate the risk of further events.

No.

To the extent that the Data Privacy and Security Policies and Procedures, provided as an Attachment, do not already do so, please answer or attach answers for the following:

- **Physical Possession and Storage of CO APCD Data Files:**
 - Describe how you will maintain an inventory of CO APCD data files and manage physical access to them for the duration of the project:

The Colorado School of Public Health will house the complete dataset with full PHI received from the data sources in a password-protected temporary database housed on a Health Data Compass Eureka instance. Eureka is a Google Cloud Platform-based analytic environment that is preconfigured to meet the HIPAA security and compliance standards of the University of Colorado Denver. The temporary database will be used to link, de-duplicate and clean data on cases identified across the various data sources, including CO APCD. After the data cleaning process is complete, a new randomly generated unique study ID number will be assigned which refers to both the study record and the data source. After the unique study ID is generated, all PHI will then be stripped away from the primary dataset for storage and the PHI-ID link files will be maintained in a separate password-protected folder on the Eureka instance. The PHI-ID link files will only be accessed for the purpose of record linkage. The de-identified

dataset (using the HIPAA definition of a de-identified dataset) will then be transferred to the data repository and the PHI-ID link data will be maintained separately.

The diabetes data repository will only include de-identified encounter level data on cases identified in our primary data sources. The data repository will contain the minimum data necessary for the project needs. The data repository will be stored on a comprehensive password-protected HIPAA-compliant database on a password-protected server at the Colorado School of Public Health. The computers of the Colorado School of Public Health research team are on a segregated network utilized specifically for data that falls under the security rules of HIPAA. The Colorado School of Public Health uses network segregation as means of data separation as per HIPAA requirements. This network is disconnected from the standard, public university network through the use of firewalling and routers. Additionally, the Colorado School of Public Health uses a system of “access control” for certain folders that are located within the HIPAA network. The folders are restricted and access is organized and granted by the IT department. Access to individual files and folders are assigned unique permissions stored in the Active Directory. The Colorado School of Public Health IT team will authorize members of the research team to have access to a specific folder housing the project data.

- Describe your personnel/staffing safeguards, including:
 - Confidentiality agreements in place with individuals identified as being assigned to this study. Include, for example, agreements between the Principal Investigator or Data Custodian and others, including research team members, and information technology and administrative staff:

Our IRB protocol and DUAs/BAA's contain specific language about confidentiality of primary datasets containing PHI which will only be accessed only by project staff at the Colorado School of Public Health for cleaning purposes.

- Staff training programs you have in place to ensure data protections and stewardship responsibilities are communicated to the research team:

As part of the Colorado School of Public Health we have mandatory training on CITI including a HIPAA course titled ‘Health information privacy and security’, responsible conduct of research, conflict of interest, and safety of human subject’s research. Records of these training are stored electronically and monitored by Human Resources at the University of Colorado.

- Procedures to track the active status and roles of each member of the research team throughout the project and a process for notifying the CO APCD of any changes to the team:

COMIRB, as this project’s IRB of record, and the CO APCD Administrator will be notified of changes to the project’s key personnel. Additionally, the Colorado School of Public Health uses a system of “access control” for certain folders that are located within the

HIPAA network. The folders are restricted and access is organized and granted by the IT department. Access to individual files and folders are assigned unique permissions stored in the Active Directory. The Colorado School of Public Health IT team will authorize *only current* members of the research team to have access to a specific folder housing the project data.

- Describe your technical and physical safeguards. Examples include:
 - Actions taken to physically secure data files, such as site and office access controls, secured file cabinets and locked offices.
 - Safeguards to limit access to CO APCD data and analytical extracts among the research team (Note: if the distribution of analytical data extracts among the researcher team is part of your data management plan, the extracts remain subject to the terms of your Data Use Agreement).

The Colorado School of Public Health computer housing the CO APCD files will be stored on a computer in locked offices. Key access to the offices is restricted to the research team and the offices are locked at all times when not occupied by the project personnel. The computers of the Colorado School of Public Health research team are on a segregated network utilized specifically for data that falls under the security rules of HIPAA. The Colorado School of Public Health uses network segregation as means of data separation as per HIPAA requirements. This network is disconnected from the standard, public university network through the use of firewalling and routers. Additionally, the Colorado School of Public Health uses a system of “access control” for certain folders that are located within the HIPAA network that will house the password-protected de-identified encounter level CHD data repository on a secure internal server. The folders are restricted and access is organized and granted by the IT department. Access to individual files and folders are assigned unique permissions stored in the Active Directory. The Colorado School of Public Health IT team will authorize members of the research team to have access to a specific folder housing the project data. Access to this folder will be restricted to the research team, and users will require passwords to access this folder. The password will be a nonsensical combination of numbers and letters, changed on a regular schedule, never repeated, and stored away from the computer.

- Provide a brief description of your policies and procedures for ensuring that CO APCD data are protected when stored on a server.
 - Describe how your organization prevents the copying or transfer of data to local workstations and other hard media devices (CDs, DVDs, hard drives, etc.). Note that Applicants are required to encrypt CO APCD data both in motion and at rest:

Datasets from CO APCD will be transmitted to the Colorado School of Public Health using SSL (Secure Sockets Layer) certification to ensure a secure file transfer on an encrypted connection – or an equivalent. Additionally, CO APCD data will be stored on a password-protected, encrypted file at the Colorado School of Public Health on

a secure internal server. The Colorado School of Public Health prevents copying or transferring of data to local workstations and other hard media devices by giving role based access to the encrypted folder such that access is limited to the study personnel only.

- Data Reporting and Publication
 - Your organization must ensure that all analytic extracts, analyses, findings, presentations, reports, and publications based on CO APCD data files adhere to specific requirements of the Data Use Agreement (DUA: refer to sections 6, 7 and 8 in the Data Use Agreement). **Briefly describe your plan for demonstrating that data reporting and publication processes will be consistent with the DUA, including adhering to CO APCD cell suppression policies:**

In compliance with the DUA, any report will adhere to the cell size suppression policy where no cell with less than eleven observations may be displayed and that no individual level records are in the report. Additionally, we will send the APCD Administrator a copy of results derived from the APCD data as requested. In compliance with the DUA we will obtain approval from the APCD Administrator to release any report or output prior to distribution outside our project team. Finally, in regards to the attempt to link records to any identifiable data, we are seeking approval to the linkage of specific files in accordance with the protocol described here. Upon completion of record linkage and de-duplication we will strip away the identifying variables and confirm there is no way to re-link the data to any form of PHI.

2. **Completion of Research Tasks and Data Destruction**

Your organization must ensure that it has policies and procedures in place to destroy the CO APCD data files upon completion of the project and that you have safeguards to ensure the data are protected when researchers terminate their participation in the research project. Describe your plan for demonstrating that your organization has policies and procedures in place to reliably destroy the data files upon completion of the research:

Our policy and procedure to reliably destroy the data files upon completion of the research adhere with the HIPAA regulation where the data files will be destroyed 7 years after IRB acknowledgement of study closure.

3. **Request for Privacy Board Approval** *(Only Applicable to Identifiable Data Requests)*

Projects that request Identifiable information for a research purpose may require approval from the DRRC acting as a Privacy Board if an IRB is not available.

- The DRRC, acting as a Privacy Board, may approve a waiver of the individual authorization normally required to release PHI under CFR § 164.508 if:
- It would be impracticable for researchers to obtain written authorization from patients that are the subject of the research; and
- The research could not practicably be conducted without access to and use of the PHI.

- The DRRC, acting as a Privacy Board, is required to evaluate certain criteria in considering whether to approve an authorization waiver. If you are requesting Identifiable Information for a research purpose, explain why your proposed use of PHI involves no more than a minimal risk to the privacy of patients that are the subject of the research. Evidence of minimal risk to the privacy of patients that should be addressed in your explanation includes:
 - An adequate plan to protect PHI identifiers from improper use and disclosure;
 - An adequate plan to destroy PHI identifiers at the earliest opportunity; and
 - Adequate written assurances that PHI will not be reused or disclosed.

Waiver of individual authorization

We request a waiver for the collection of CO APCD and the reasons for this request are three-fold:

Minimal Risk. The risk to individuals resulting from this no-contact secondary data abstraction process is minimal. Study staff will access only records which have high likelihood of diabetes consistent our case finding definition. From this subset of records limited information will be abstracted. While PHI will be abstracted, it will be collected and stored with secure methods on HIPAA-compliant database at the Colorado School of Public Health.

Study Practicability. This surveillance data repository of multiple retrospective administrative data sources is not amenable to direct contact and consenting of individuals. In most cases there is no current contact information and efforts to locate individuals could be construed as prohibitively invasive of individual privacy.

Need for PHI. The ultimate aim of this surveillance data repository is to facilitate future population-level surveillance to determine prevalence and outcomes on adolescents and adults with diabetes. Because of the fragmented nature of current surveillance and health care utilization data, combining and de-duplicating data sources is absolutely necessary to accomplish this aim.

Plan regarding protection and destruction of PHI

This is a no-contact analysis of secondary administrative data and historical electronic medical data. No treatment, intervention or procedures will be administered by the study. The purpose of the study is public health surveillance. The risk around obtaining PHI is minimized in several ways:

- All unique identifiers will be used solely in the record-linkage phase where we seek to identify individuals who are in one or more of the data sources (i.e. clinical records from other data sources).
- Once linkage has been accomplished, new study ID numbers will be assigned, and the PHI variables will be removed, making the main dataset de-identified.
- The file linking PHI to the study ID will be maintained for the duration of the surveillance system in a separate, password-protected, encrypted file on a secure server at the Colorado School of Public Health to ensure there is no way to re-link to any form of PHI. PHI will not be reused or disclosed.
- PHI will be destroyed at the earliest possible opportunity and in compliance with HIPAA regulations.

Appendix I

Certification of Project Completion and Destruction or Retention of Data

(Please Save)

Name:	
Title:	
Organization:	
Address:	
Tel Number:	
Fax Number:	
E-mail Address;	
Project Title:	
Data Sets:	
Years:	
<input type="checkbox"/> Certification of Data Destruction	Date the Data was Destroyed:
<input type="checkbox"/> Request to Retain Data	Date Until Data Will Be Retained:

Instructions: Data must be destroyed so that it cannot be recovered from electronic storage media in accordance with the methods established by the “Guidance to Render Unsecured Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals,” as established by the U.S. Department of Health and Human Services (HHS).

I hereby certify that the project described in the Application is complete as of this date _____, ___, 20__.

Complete the appropriate section, below:

☐ I/we certify that we have destroyed all Data received from the CO APCD Administrator in connection with this project, in all media that were used during the research project. This includes, but is not limited to data maintained on hard drive(s), diskettes, CDs, etc.

☐ I/we certify that we are retaining the data received in connection with the aforementioned project, pursuant to the following health or research justification (provide detail, use as much additional space as necessary and state how long the data will be retained).

☐ I/we hereby certify that we are retaining the Data received from the APCD Administrator in connection with the aforementioned project, as required by the following law. [Reference the appropriate law and indicate the timeframe].

By signing this Agreement, the Receiving Organization agrees to abide by all provisions set out in this Agreement.

SIGNATURES:

For the CO APCD:	For Receiving Organization:
Signature:	Signature: <i>Jessa Crume</i>
Name: Pete Sheehan	Name: Tessa Crume
Title: VP of Client Solutions & State Initiatives	Title: Co-PI SEARCH-DiCAYA, Associate Professor