

STATE OF COLORADO

John W. Hickenlooper, Governor
Larry Wolk, MD, MSPH
Executive Director and Chief Medical Officer

Dedicated to protecting and improving the health and environment of the people of Colorado

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Colorado Department
of Public Health
and Environment

COLORADO IMMUNIZATION INFORMATION SYSTEM DATA USE AGREEMENT - RESEARCH

The Colorado Immunization Information System (CIIS) Program of the Colorado Department of Public Health and Environment (CDPHE) maintains immunization information within the state immunization registry that is confidential in accordance with Colorado Revised Statute (CRS) § 25-4-2403. CIIS is a confidential, computerized, population-based system that collects and consolidates immunization data from a variety of sources and provides tools for designing and sustaining effective immunization strategies at the provider and program levels. CDPHE recognizes that it may become necessary in the course of conducting legitimate research on the treatment, control, investigation, and prevention of diseases and conditions dangerous to the public health for a researcher or specifically authorized person to obtain potentially identifying data from confidential records held by CDPHE. Access to potentially identifying information **may** be provided if all of the following conditions are met:

1. All data provided to the researcher are the property of CDPHE.
2. Researchers will provide complete information about the aims and intentions of the research, as well as the names of all persons who will have access to the confidential information, by completing all items in the *CIIS Request for Data Form* on page 4. CIIS requires submission of a detailed study protocol including the following information: background, anticipated scientific benefits, target population, sample size(s), Institutional Board Review (IRB) approval status, specific research questions, procedures to be used to ensure confidentiality of the data, and the form in which, and to whom, results of the study results will be released.
3. Copies of records or other materials containing confidential information are not to be made without the specific, written approval of CIIS. This also applies to making copies of electronic data.
4. Use of confidential information is strictly limited to the conditions defined in this agreement. Researchers shall limit access to confidential information strictly to those individuals or classes of individuals who shall have access in order to perform the duties set forth in the application, and each of these individuals shall read and sign this Data Use Agreement.
5. Researchers agree to take appropriate administrative, technical, and physical safeguards to protect the data from any unauthorized use or disclosure not provided for in this Agreement. Researchers shall ensure that no identifying information is transmitted through unsecured communications, including e-mail or other unsecured Internet connections.

6. Within 48 hours of the Researcher’s discovery, the Researcher shall report to CIIS any use or disclosure of the confidential information that violates either the Data Use Agreement or applicable state or federal laws or regulations.
7. No confidential information shall be publicly released. Furthermore, any reports or aggregate tabulations that are prepared shall suppress all counts and rates where the number, the numerator, or the denominator is smaller than three.
8. Records shall be destroyed or returned to CIIS upon completion of the work described in the application. The Data User agrees to send CIIS written notification that the data have been destroyed or returned within 30 days of the completion of work described in the application unless CIIS provides a specific date for destruction or return.
9. Researchers attest that the confidential information requested represents the minimum information necessary for the Researcher to perform duties described in the application and that only the minimum necessary individuals shall have access to the confidential information in order to perform such work.
10. Researchers agree to furnish a research protocol and all documentation concerning IRB reviews and to submit required documentation to an IRB or Privacy Board should research protocols change. Researchers also agree to submit to CIIS any change in either the waiver status or conditions for IRB approval of the project related to work described in the application.
11. Researchers shall include at least one Colorado Immunization Section staff member as an author on any publications using data provided by CIIS, unless CIIS declines the researcher’s offer to be included. Any release of results from the research project derived from CIIS data is to be in accordance with the terms of this agreement and must be **submitted by the researcher to CIIS for review and approval prior to release**. The following statement is to be included in the release of data derived from CIIS records:

“These data were supplied in part by the Colorado Immunization Information System of the Colorado Department of Public Health and Environment, which specifically disclaims responsibility for any analyses, interpretations, or conclusions based on the given data.”

In addition, Researchers shall notify CIIS when the publication or presentation is available and, further, shall provide a final copy of the product produced using CIIS data.

Violation of these conditions shall automatically result in both the voiding of this agreement and the refusal of future research requests. Violations of these conditions may also result in legal prosecution per CRS §25-4-2403(5).

I agree with the conditions for access to and use of confidential immunization information.

Principle Investigator	Signature	Date
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Print Name	Signature	Date
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Print Name	Signature	Date
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Print Name	Signature	Date
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Print Name	Signature	Date
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(By signing, the Principle Investigator and key staff accessing CIIS data certify to the best of his/her knowledge that the information provided is accurate and all data requested is necessary for the stated purpose.)

Instructions

1. Prepare a copy of the detailed study protocol with all required information as described in item 2.
2. Complete the questions as outlined on the *Request for Data Form* of this agreement and have all persons who would access the data sign and date.
3. Person making request must initial all pages of this document.
4. Submit the completed/signed form and along with the detailed study protocol to Heather Shull, CIIS Program Manager at heather.shull@state.co.us. The information provided here, combined with the study protocol, will be the basis on which a decision will be made to provide access to CIIS immunization records.
5. **Incomplete requests will not be accepted.**
6. Signature by the CIIS Program Manager or Immunization Section Director will constitute the agreement between the requester(s) and CIIS. This will permit access to information for the selected records, specify the limits of such access, and define the use of information obtained from the records.
7. Written notice of CIIS's decision will not exceed 30 days.

CIIS Program Approval

Print Name	Signature	Date
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**COLORADO IMMUNIZATION INFORMATION SYSTEM
REQUEST FOR DATA FORM**

DATE: _____

CONTACT INFORMATION:

Organization:	
Type of Organization:	
Project Title (if applicable):	
Principle Investigator:	
Name of Person Requesting Data:	
Phone:	
Fax:	
Email Address:	
Address:	
City, State Zip:	

REQUESTED DATE TO RECEIVE DATA? *(Requests will be processed as time permits)*

TYPE OF DATA NEEDED?

- Limited Dataset *(e.g., All provider types by county)*
- De-identified Aggregate Data
- Record level data that includes protected health information (PHI)

DATA FORMAT: MS Access SAS Data Set CVS Flat File Excel*

**Excel files only have 64K records on a worksheet; large datasets are not easily generated using this format.*

THROUGH WHAT DATE WILL IS THE DATA NEEDED?

- Will look up data manually
 - One-time Export
 - Multiple Exports
- Frequency: Weekly Monthly Bi-monthly Quarterly Annually

DEFINE THE SPECIFIC INFORMATION REQUESTED (including data year(s) and all variables):

SUMMARIZE THE PURPOSE OR USE OF THE DATA REQUESTED: *(Include how use of the data benefits the mission and goals of CDPHE.)*

SUMMARIZE THE FINAL OUTCOME(S) AND/OR RESULTS FROM THIS DATA: *(e.g., reports, presentations, compliance with statute, etc.)*

LIST ALL INDIVIDUALS (NAMES & TITLES) WHO ARE MAY ACCESS THE DATA:

SUMMARIZE THE POLICIES AND PROCEDURES YOU HAVE IN PLACE TO PROTECT AND SAFEGUARD THE DATA.