CHIA
center for health information and analysis

CHIA Non-Governmental Application for Massachusetts Case Mix Data [Exhibit A: Data Application]

I. INSTRUCTIONS

This form is required for all Applicants, except Government Agencies as defined in 957 CMR 5.02. All Applicants must also complete the Data Management Plan, attached to this Application. The Application and the Data Management Plan must be signed by an authorized signatory of the Organization. This Application and the Data Management Plan will be used by CHIA to determine whether the request meets the criteria for data release, pursuant to 957 CMR 5.00. Please complete the Application documents fully and accurately. Prior to receiving CHIA Data, the Organization must execute CHIA's Data Use Agreement. Applicants may wish to review that document prior to submitting this Application.

Before completing this Application, please review the data request information on CHIA's website:

- Data Availability
- Fee Schedule
- Data Request Process

After reviewing the information on the website and this Application, please contact CHIA at casemix.data@state.ma.us if you have additional questions about how to complete this form.

All attachments must be uploaded to IRBNet with your Application. All Application documents can be found on the CHIA website in Word and in PDF format or on IRBNet in Word format. If you submit a PDF document, please also include a Word version in order to facilitate edits that may be needed.

Applications will not be reviewed until the Application and all supporting documents are complete and the required application fee is submitted. A Fee Remittance Form with instructions for submitting the application fee is available on the CHIA website and IRBNet. If you are requesting a fee waiver, a copy of the Fee Remittance Form and any supporting documentation must be uploaded to IRBNet.

II. ORGANIZATION AND INVESTIGATOR INFORMATION

Project Title:	Prescription drug monitoring programs and opioid-related harm
IRBNet Number:	861593-1
Organization Requesting Data:	Violence Prevention Research Program at the University of California Davis Health
Organization Website:	**https://www.ucdmc.ucdavis.edu/vprp/**
Authorized Signatory for Organization:	**Annie Wong**
Title:	Director, UC Davis Health Contracts
E-Mail Address:	pkvang@ucdavis.edu
Address, City/Town, State, Zip Code:	Sherman Building, Suite 2300 University of California Davis Health 2315 Stockton Blvd., Sacramento, CA 95817 (Reference Agreement No. S16-00492D)
Primary Investigator:	

Title:	Magdalena Cerdá
E-Mail Address:	cerda@ucdavis.edu
Telephone Number:	916 734 3539
Names of Co-Investigators:	Garen Wintemute, MD, Professor, Dr. Silvia Martins, Dr. Paul Gruenewald
E-Mail Addresses of Co-Investigators:	Garen Wintemute: gjwintemute@ucdavis.edu Paul Gruenewald: paul@PREV.org

III. FEE INFORMATION

1. Consult the Fee Schedule for Case Mix and Charge Data and select one of the following options:

☒ Researcher
☐ Other
☐ Reseller

2. Are you requesting a fee waiver?

☐ Yes
☒ No

3. Complete and submit the Fee Remittance Form. If requesting a fee waiver, submit a letter stating the basis for your request (if required). Please refer to the Fee Schedule (effective Feb 1, 2017) for fee waiver criteria.

IV. PROJECT INFORMATION

1. What will be the use of the CHIA Data requested? [Check all that apply]

☒ Epidemiological	☐ Health planning/resource allocation	☐ Cost trends
☒ Longitudinal Research	☐ Quality of care assessment	☐ Rate setting
☐ Reference tool	☒ Research studies	☐ Severity index tool
☐ Surveillance	☐ Student research	☐ Utilization review of resources
☐ Inclusion in a product	☒ Other (describe in box below)	

To assess the impact of implementation of specific prescription drug monitoring program (PDMP) "best practice" characteristics on prescription opioid (PO) and prescription opioid overdose and heroin overdose (POD and HOD) in 1993-2014

2. Provide a summary of the specific purpose and objectives of your Project. This may include research questions and/or business use Projects.

This study proposes to assess the impact of implementation of specific PDMP "best practice" characteristics on PO and heroin overdose (POD and HOD) in 1993-2014. Our specific aims are:

1. To test the relation between implementation of "best practice" PDMP features and change in POD and HOD.
H1: The incidence of POD decreased with the introduction of "best practice" PDMP characteristics

H2: The incidence of HOD increased with the introduction of "best practice" PDMP characteristics
2. To test whether the relationship between implementation of PDMP "best practice" characteristics and POD and HOD differed by medical need and socioeconomic characteristics of population groups
H1: Populations living in areas with a higher concentration of groups with medical need for POs (e.g., arthritis and cancer patients, manual labor industries) and populations living in more affluent areas experienced a greater reduction in POD with the introduction of "best practice" PDMP characteristics
H2: Populations living in less affluent areas experienced a greater increase in HOD with the introduction of "best practice" PDMP characteristics than populations living in more affluent areas.

We are requesting this data to support research conducted under our National Institute on Drug Abuse grant, "Prescription drug monitoring programs and opioid-related harm" (R01DA040924). In conjunction with Healthcare Cost and Utilization Project (HCUP) data, these data will allow us to analyze annual counts of opioid and heroin-related hospital discharges, localized by residential zip code, county, and state and to examine local impacts of state-level PDMP characteristics over time. Our study population includes all individuals admitted to community hospitals in 23 states (including Massachusetts) between 1993 and 2014.

Our project research questions are:
1. What is the impact of PDMPs on health outcomes?
2. Do variations in PDMP characteristics affect outcomes?
3. Who benefits the most from PDMPs?
4. Can PDMPs have unintended negative consequences?

To test these aims and answer our research questions, we are developing a typology of PDMP characteristics. Characteristics examined will include number of drug schedules reported, frequency of data reporting, proactive provision of data to authorized users, requirements for user training, registration, and data accessing, and interstate data sharing. We will assess compliance to PDMP "best practices" by determining the provider query rate for each state. Inpatient overdose data geocoded to the zip code. We will test the impact of variations in PDMP characteristics on rates of hospitalizations due to PO and heroin overdose.

3. Has an Institutional Review Board (IRB) reviewed your Project?
☒ Yes [*If yes, a copy of the approval letter and protocol must be included with the Application package on IRBNet.*]
☐ No, this Project is not human subject research and does not require IRB review.

4. **Research Methodology**: Applicants must provide either the IRB protocol or a written description of the Project methodology (typically 1-2 pages), which should state the Project objectives and/or identify relevant research questions. This document must be included with the Application package on IRBNet and must provide sufficient detail to allow CHIA to understand how the Data will be used to meet objectives or address research questions.

V. PUBLIC INTEREST

1. Briefly explain why completing your Project is in the public interest. *Uses that serve the public interest under CHIA regulations include, but are not limited to: health cost and utilization analysis to formulate public policy; studies that promote improvement in population health, health care quality or access; and health planning tied to evaluation or improvement of Massachusetts state government initiatives.*

The findings from this study will inform researchers and policymakers about the types of PDMP characteristics that would lead to the greatest reduction in PO-related harm, and identify potential unintended consequences of PDMP characteristics in terms of heroin-related harm and exacerbating socioeconomic disparities in PO and heroin-related problems. This type of research can help policymakers in Massachusetts decide how to better deploy scarce overdose-prevention resources: (1) to invest funds in adopting specific PDMP characteristics that result in the greatest reductions in PO-related harm, and (2) to modify PDMP characteristics that increase socioeconomic disparities in PO overdose and result in increased heroin-related overdose.

VI. DATASETS REQUESTED

1. Specify below the dataset(s) and year(s) of data requested for this Project, and your justification for requesting *each* dataset.

☒ **Hospital Inpatient Discharge Data**

☒2004 ☒2005 ☒2006 ☒2007 ☒2008 ☒2009 ☒2010 ☒2011 ☒2012 ☒2013 ☒2014 ☒2015

Describe how your research objectives require Inpatient Discharge data:

Hospital-based discharge data offer several advantages:
1) They focus on severe cases that have been vetted using more uniform standards and better ICD-9 coding of conditions than emergency department admissions. HCUP hospitalization data is highly accurate, has been rigorously tested, and is widely used to estimate diagnoses. With this data, we can reliably evaluate whether PDMP "best practices" have an impact on serious, non-fatal, manifestations of PO and heroin use, particularly overdose, rather than just on use or just fatal overdose.
2) Hospital discharge data is available on an annual basis across a large sample of states with pre- and post-PDMP data. Emergency department data was only available for 9 states with pre- and post-PDMP data.
3) It is possible to obtain individual hospital discharge records and to estimate rates at small geographic areas such as the zip code. This is critical if we are to evaluate heterogeneity in the impact of PDMP "best practices" by the concentration of people with medical need for POs and by socioeconomic characteristics in local areas, and if we are to account for key time-varying confounders that vary across local areas and that influence the relationship between PDMP "best practices" and our outcomes of interest.

☐ **Outpatient Observation Data**

☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☐2012 ☐2013 ☐2014 ☐2015

Describe how your research objectives require Outpatient Observation data:

☐ **Emergency Department Data**

☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☐2012 ☐2013 ☐2014 ☐2015

Describe how your research objectives require Emergency Department data:

2. Case Mix and Charge Data are updated each fiscal year. As certain Project objectives may require future years of data not yet available, CHIA will consider requests for additional fiscal years of the *same data (i.e., same elements and files)* without the need to submit a new application. Please note that approved requests will be subject to the Data Use Agreement and fees for additional data. Please indicate below whether this is a one-time request, or if the described Project will require future years of Data and if so, which years.

☐ One-Time **OR** ☒ 2016 ☒ 2017 ☒ 2018 ☒ 2019 ☐ 2020

VII. DATA ELEMENTS REQUESTED

State and federal privacy laws limit the release and use of Data to the minimum amount of data needed to accomplish a specific Project objective.

Case Mix and Charge Data are grouped into six "Levels" or Limited Data Sets (LDS) for release, depending on the fiscal year. Data for FY 2004 – 2014 are organized into Levels. Level 6 Data will be released to Government Applicants only. *CHIA staff will use the information provided in this section to determine the appropriate Level of Data justified for release.*

Data for FY 2015 and later are organized into LDS's. All applicants receive the "Core" LDS, but may also request additional elements listed below for inclusion in their analyses. Requests for additional elements will be reviewed by CHIA to determine whether each represents the minimum data necessary to complete the specific Project objective.

For a full list of elements in the release (i.e., the "Core" elements and additional elements), please refer to release layouts, data dictionaries and similar documentation included on CHIA's website.

1. Specify below which elements you are requesting in addition to the "Core" LDS. CHIA will use this information to determine what Level of data is needed for pre-FY 2015 data requests.

Geographic Data

The geographic sub-divisions listed below are available for CT, MA, ME, NH, RI, VT, and NY residents only for FY 2015 and after. Fiscal years 2004 – 2014 will contain the geographic sub-divisions listed below for all states. Choose *one* of the following geographic options.

☐ 3-Digit Zip Code (Standard)	☐ 3-Digit Zip Code & City/Town ***	☒ 5-Digit Zip Code ***	☐ 5-Digit Zip Code & City/Town ***

*****If requested, provide justification for requesting 5-Digit Zip Code or City/Town. Refer to specifics in your methodology:**

We need zip codes in order to answer one of the two main questions in our study. One of the main aims of our study is to examine whether the relationship between the implementation of prescription drug monitoring program (PDMP) "best practice" characteristics and opioid overdoses differs by the medical need and socioeconomic characteristics of local population groups. We hypothesize that the benefit of PDMPs is likely not uniform across the population of opioid users, and may be concentrated among populations with greater access to the health care system — that is, among those with a medical need for prescription opioids. In contrast, we also hypothesize that the reduction in prescription opioid supply associated with the instatement of PDMPs may have unintended consequences, potentially leading to heroin use among those who abuse prescription opioids in less affluent areas, where the access to treatment for opioid dependence is lower.

To answer these questions, we need to measure the rate of opioid overdose-related discharges in small local areas (i.e., zip codes), and see how the impact of PDMPs differs by the characteristics of these small local areas. In other words, we need to see whether the effect of PDMPs on overdose-related discharges is different in zip codes with more medical need for opioids, and to see whether the effect of PDMPs on overdose-related discharges is different in less socioeconomically affluent zip codes. **Zip codes were chosen as the unit of analysis because they are the most resolved geographic unit at which hospital discharges across states were identified.**

In addition, zip codes offer other advantages that improve our ability to answer our key study question, about the impact of PDMP "best practice" characteristics on opioid-related overdoses. If we have zip codes, we can set up models

that (1) test changes in opioid overdoses over time both within and across states; (2) account for relevant predictors of opioid use at the state, county, and zip code levels; (3) control for the clustering of opioid overdose rates within zip codes within countries within states; and (4) address small-area effects (e.g., extreme outliers estimated among small populations in sparsely settled zip codes; and (5) estimate the extent of spatial autocorrelation in opioid overdose that may be related to spatial contagion (i.e., similarity of rates between adjacent geographic units). We know from examining hospital discharge data in other states that failures of spatial independence are quite large and need to be accounted for in order to obtain accurate estimates. If we had to use less resolved units such as counties or states, we would end up obtaining reduced statistical estimates of effects due to aggregation bias. In fact, all prior studies on the impact of PDMPs on overdoses only use state-level data, and we would argue, for that reason, are quite limited by a failure to account for important sources of confounding, heterogeneity, and spatial dependence within states. By using zip code level data, we will be able to greatly improve our ability to identify the causal effect of PDMP characteristics on overdose rates.

To assure confidentiality we will not report any record level data from areas with fewer than 11 cases. In presentations and publications of statistical modeling results we will take care to insure that any small area subject to this constraint be excluded from presentation. Thus, the statistical models applied in quantitative analyses of these data will make full use of all cases, model parameters and credible intervals will reflect the use of all cases, but presentations of the data themselves will be subject to constraint and small areas, to the extent they arise if at all, will be masked in reporting.

Demographic Data

Choose *one* of the following demographic options:

☐ Not Requested (Standard)	☒ Race & Ethnicity***

**** If requested, provide justification for requesting Race and Ethnicity. Refer to specifics in your methodology:**

To study sources of variation in substance abuse. As mentioned above, to assure confidentiality we will not report any record level data from areas with fewer than 11 cases. In presentations and publications of statistical modeling results we will take care to insure that any small area subject to this constraint be excluded from presentation. Thus, the statistical models applied in quantitative analyses of these data will make full use of all cases, model parameters and credible intervals will reflect the use of all cases, but presentations of the data themselves will be subject to constraint and small areas, to the extent they arise if at all, will be masked in reporting.

Dates

Choose *one* option from the following options for dates of admissions, discharges, and significant procedures:

☐ Year (YYYY)(Standard)	☐ Month (YYYYMM) ***	☒ Day (YYYYMMDD)***

*****If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology:**

To track temporal patterns in substance abuse.

Practioner Identifiers (UPN)

Please choose *one* of the following options for Practioner Identifier(s):

☒ Not Requested (Standard)	☐ Hashed ID ***	☐ Board of Registration in Medicine

		Number(BORIM) ***
***If requested, provide justification for requesting Hashed ID or BORIM Number. Refer to specifics in your methodology:		

Unique Health Information Number (UHIN)
Please choose *one* of the following:

☒ Not Requested (Standard)	☐ UHIN Requested ***
*** If requested, provide justification for requesting UHIN. Refer to specifics in your methodology:	

Hashed Mother's Social Security Number
Please choose *one* of the following:

☒ Not Requested (Standard)	☐ Hashed Mother's SSN Requested ***
*** If requested, provide justification for requesting Hashed Mother's SSN. Refer to specifics in your methodology:	

VIII. DATA LINKAGE

Data linkage involves combining CHIA Data with other data to create a more extensive database for analysis. Data linkage is typically used to link multiple events or characteristics within one database that refer to a single person within CHIA Data.

1. Do you intend to link or merge CHIA Data to other data?
   - ☒ Yes
   - ☐ No linkage or merger with any other data will occur

2. If yes, please indicate below the types of data to which CHIA Data will be linked. [Check all that apply]
   - ☐ Individual Patient Level Data (e.g. disease registries, death data)
   - ☐ Individual Provider Level Data (e.g., American Medical Association Physician Masterfile)
   - ☐ Individual Facility Level Data (e.g., American Hospital Association data)
   - ☒ Aggregate Data (e.g., Census data)
   - ☐ Other (please describe):

3. If yes, describe the data base(s) to which the CHIA Data will be linked, indicate which CHIA Data elements will be linked and the purpose for each linkage.

We will link hospital discharge data with zip code level demographic information from Geolytics. This linkage will allow to estimate zip rates of prescription opioid (PO) and heroin overdoses. This linkage will also allow identify populations with potential medical need for POs (i.e. PO need due to chronic disease and to workplace injury) and measures of socioeconomic distribution to denote potential modifiers of the relationship between PDMP characteristics and PO and heroin overdose. Which will ultimately allow us to test whether the relationship between implementation of PDMP

"best practice" characteristics and POD and HOD differed by medical need and socioeconomic characteristics of population groups.

4. If yes, for each proposed linkage above, please describe your method or selected algorithm (e.g., deterministic or probabilistic) for linking each dataset. If you intend to develop a unique algorithm, please describe how it will link each dataset.

Deterministic, using the 5-digit zipcode variable

5. If yes, please identify the specific steps you will take to prevent the identification of individual patients in the linked dataset.

We will not report any record level data from areas with fewer than 11 cases. In presentations and publications of statistical modeling results we will take care to insure that any small area subject to this constraint be excluded from presentation. Thus, the statistical models applied in quantitative analyses of these data will make full use of all cases, model parameters and credible intervals will reflect the use of all cases, but presentations of the data themselves will be subject to constraint and small areas, to the extent they arise if at all, will be masked in reporting.

IX. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Describe your plans to publish or otherwise disclose CHIA Data, or any data derived or extracted from CHIA Data, in any paper, report, website, statistical tabulation, seminar, conference, or other setting. Any and all publication of CHIA Data must comply with CHIA's cell size suppression policy, as set forth in the Data Use Agreement. Please explain how you will ensure that any publications will not disclose a cell less than 11, and percentages or other mathematical formulas that result in the display of a cell less than 11.

In presentations and publications of statistical modeling results we will take care to ensure that any small area subject to this constraint be excluded from presentation. Further, please note that we will not link patient records to specific hospitals, and will not present any data on specific hospitals – rather, our study focuses on aggregate patient characteristics at the zip code level. Additionally, we will not release or disclose, and will take all necessary and reasonable precautions to prohibit others from releasing or disclosing, any information that directly or indirectly identifies individuals ororganizations.

2. Do you anticipate that the results of your analysis will be published and/or made publically available? If yes, describe how an interested party will obtain your analysis and, if applicable, the amount of the fee, that the third party must pay.

Results will be published on peer reviewed journals and presented at scientific conferences such as the College on Problems of

Drug Dependence and the Society for Epidemiologic Research. Results may also be presented in press releases to the media. If any party is interested in learning more about the project results they may contact the study PI, Dr. Magdalena Cerdá, for information.

3. Will you use CHIA Data for consulting purposes?
- ☐ Yes
- ☒ No

4. Will you be selling standard report products using CHIA Data?
- ☐ Yes
- ☒ No

5. Will you be selling a software product using CHIA Data?
- ☐ Yes
- ☒ No

6. Will you be reselling CHIA Data in any format?
- ☐ Yes
- ☒ No

If yes, in what format will you be reselling CHIA Data (e.g., as a standalone product, incorporated with a software product, by a subscription, etc.)?

7. If you have answered "yes" to questions 4, 5 or 6, please describe the types of products, services or studies.

8. If you have answered "yes" to questions 4, 5, or 6, what is the fee you will charge for such products, services or studies?

X. INVESTIGATOR QUALIFICATIONS

1. Describe your previous experience using hospital data. This question should be answered by the primary investigator and any co-investigators who will be using the Data.

Dr. Magdalena Cerdá, Associate Professor, is the PI for this study. Dr. Cerdá has conducted multiple studies examining the role that policy measures and features of the local neighborhood environment play in shaping substance use and associated risk behaviors and has particular expertise in the area of nonmedical prescription opioid use. This study builds on recent research she conducted on the epidemiology of prescription opioid-induced overdose fatalities in New York City, focusing on the influence of neighborhood conditions on overdose mortality.

Garen Wintemute, MD, Professor, Co-Investigator for this study has been involved in the study of violence and its prevention for more than 20 years. Substance abuse is an important risk factor for both intentional and unintentional

injury and he recently authored or co-authored structured reviews of the literature on controlled substance and alcohol misuse as risk factors for violence. He will contribute to the translational aspects of the project, working with public health and criminal justice agencies, policymakers, and organizations such as the PDMP Center of Excellence to implement PDMP-based prevention measures, clinical and public health program changes, and other interventions based on these findings.

Dr. Paul Gruenewald is Scientific Director & Senior Research Scientist at Prevention Research Center. He has three decades of experience developing and testing population and multilevel models of the environmental correlates and determinants of substance use and related problems, with an emphasis upon studies of alcohol availability and related problems. He will be applying this background and these skills to support the GIS and spatial analysis needs of the current project. In collaboration with Dr. Cerdá and project staff, he will be responsible for managing and overseeing acquisition of HCUP, Census, and other related archival data, monitoring the development of the project geographic information system, advising on the development and testing of Bayesian Poisson conditional autoregressive space-time misalignment models, and on the formulation of spatial analysis systems for testing project hypotheses.

2. **Resumes/CVs**: When submitting your Application package on IRBNet, include résumés or curricula vitae of the principal investigator and co-investigators. (These attachments will not be posted on the internet.)

XI. USE OF AGENTS AND/OR CONTRACTORS

By signing this Application, the Agency assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors. The Agecny must have a written agreement with the agent of contractor limiting the use of CHIA Data to the use approved under this Application as well as the privacy and security standards set forth in the Data Use Agreement. CHIA Data may not be shared with any third party without prior written consent from CHIA, or an amendemtn to this Application. CHIA may audit any entity with access to CHIA Data.

Provide the following information for **all** agents and contractors who will work with the CHIA Data. *[Add agents or contractors as needed.]*

AGENT/CONTRACTOR #1 INFORMATION	
Company Name:	Prevention Research Center (PRC)
Company Website:	http://www.prev.org/
Contact Person:	Paul J. Gruenewald
Title:	Scientific Director, Senior Research Scientist
E-mail Address:	paul@prev.org
Address, City/Town, State, Zip Code	180 Grand Avenue Suite 1200 Oakland, CA 94612
Telephone Number:	510.486.1111
Term of Contract:	4/15/2016 – 4/31/2019

1. Describe the tasks and products assigned to the agent or contractor for this Project and their qualifications for completing the tasks.

PRC is responsible of compiling census unit, ZIP code, county and state electronic map files across 21 years for 23 states, including Massachusetts. PRC is also responsible for developing population misalignment metrics by state and zip code areas by year and design the Bayesian Poisson CAR misalignment models used to answer the questions and fulfill the aims of this research.

Dr. Paul Gruenewald is a co-Investigator of this study. As mentioned above, he has three decades of experience developing and testing population and multilevel models of the environmental correlates and determinants of substance use and related problems, with an emphasis upon studies of alcohol availability and related problems. He will be applying this background and these skills to support the GIS and spatial analysis needs of the current project.

2. Describe the Organization's oversight and monitoring of the activities and actions of the agent or contractor for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or contractor has access.

Weekly meetings between the principal investigator and PRC to monitor progress and ensure upholding the security of CHIA data . PRC has also ensured that the staff accessing the data use password-protected desktop and/or laptop client computers equipped with software packages appropriate to their responsibilities.

The security measures PRC uses to maintain and store the requested data are:

- **System**
  Networked computer system protected from the viruses, malware, network intrusion, and unauthorized access threats by the latest version of Symantec Endpoint Protection. All computers and servers on this network are automatically updated with the latest operating system and application level patches. All staff are required to have unique logons to control access and can only access their own profile and folders to which they have been specifically granted access. Sensitive data will be excluded from network backups.

- **Hardware/Software**
  Discharge-specific raw data will be maintained on an encrypted removable hard drive kept separate from the local desktop computer and network. When not in use this removable hard drive will be stored in a locked room. The zip-code level count data will be maintained on a networked desktop computer on a private and secure network separated from the public internet.

- **Access Control**
  Network and workstation access is restricted to authorized users with unique logon. While not in use a computer is locked, with screen saver locks requiring password after 15 minutes of inactivity.

- **Physical Environment**
  The discharge-specific raw data will be maintained on an encrypted removable hard drive stored in a locked room. The zip-code level count data will be maintained on a local desktop computer located in a locked office. All data will be located in a suite protected by electronic access controls, within a building with access controls and 24 hour security.

- **Data Storage**
  The original patient-level data files will only be used to create annual zip-code level counts of both total hospitalizations and discharges with specific ICD-9 codes (e.g. opioid abuse, opioid poisoning, or other conditions that often lead to use of prescription opioid medications such as arthritis). The original patient-level data will be stored on an encrypted removable hard drive, which will be stored in a locked room when not in use. The zip code level files with patient count data will be stored on a password-protected workstation on a secure network as described above.

- **Encryption**
  Patient-level data files with individually-identifiable will be encrypted with a key length of at least 256 bits.

3. Will the agent or contractor have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database?

☐ Yes
☒ No

4. If yes, a separate Data Management Plan **must** be completed by the agent or contractor.

AGENT/CONTRACTOR #2 INFORMATION	
Company Name:	
Company Website:	
Contact Person:	
Title:	
E-mail Address:	
Address, City/Town, Zip Code	
Telephone Number:	
Term of Contract:	

1. Describe the tasks and products assigned to the agent or contractor for this Project and their qualifications for completing the tasks.

2. Describe the Organization's oversight and monitoring of the activities and actions of the agent or contractor for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or contractor has access.

3. Will the agent or contractor have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database?

☐ Yes
☒ No

4. If yes, a separate Data Management Plan **must** be completed by the agent or contractor.

XII. ATTESTATION

By submitting this Application, the Organization attests that it is aware of its data use, privacy and security obligations imposed by state and federal law *and* confirms that it is compliant with such use, privacy and security standards. The Organization further agrees and understands that it is solely responsible for any breaches or unauthorized access, disclosure or use of CHIA Data including, but not limited to, any breach or unauthorized access, disclosure or use by any third party to whicih it grants access.

Applicants approved to receive CHIA Data will be provided with Data following the payment of applicable fees and upon the execution of a Data Use Agreement requiring the Organization to adhere to processes and procedures designed to prevent unauthorized access, disclosure or use of data.

By my signature below, I attest: (1) to the accuracy of the information provided herein; (2) that the requested Data is the minimum necessary to accomplish the purposes described herein; (3) that the Organization will meet the data privacy and security requirements described in this Application and supporting documents, and will ensure that any third party with access to the Data meets the data use, privacy and security requirements; and (4) to my authority to bind the Organization.

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA ON BEHALF OF UNIVERSITY OF CALIFORNIA DAVIS HEALTH

Signature: (Authorized Signatory for Organization)	
Printed Name :	Annie Wong, Director, UC Davis Health Contracts 7.20.2017

Attachments

A completed Application must have the following documents attached to the Application:

☐ 1. IRB approval letter and protocol (if applicable)
☐ 2. Research Methodology (if protocol is not attached)
☐ 3. CVs of Investigators
☐ 4. Data Management Plan (including one for each agent or contractor that will have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database)

Applications will not be reviewed until they are complete, including all attachments.

TRACKING TABLE (to be completed by CHIA staff only)	
Complete Application Received	
Application Fee Received	
Data Privacy Committee Review	
Data Release Committee Review	
Linkages Approved (as described)	
Approved for additional years of data	
Executive Director Approval	
Data Fee Received	
Date of First Audit	
IT Extract #	

Attachment #1 – IRB Approval Letter & Protocol or Research Methodology

UNIVERSITY OF CALIFORNIA, DAVIS

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OFFICE OF RESEARCH
IRB Administration
TELEPHONE: 916 703-9151
FAX: 916 703-9160

02/08/2016

PI: Magdalena Cerda, DrPH

Dear Dr. Cerda:

On 02/08/2016 the IRB reviewed the following protocol:

Type of Review:	Initial
Title:	Prescription drug monitoring programs and opioid-related harm
Investigator:	Magdalena Cerda, DrPH
IRB ID:	861593-1
Funding:	NIDA
Grant ID and Title:	1R01DA03996200-1A1 Prescription drug monitoring programs and opioid-related harm
IND, IDE or HDE:	None
Documents Submitted:	UC Davis - Initial Review Application HRP-226 HRP 503 - initial submission grant Application

The IRB approved the protocol from 02/08/2016 to 02/07/2017 inclusive.

Risk Determination:	No More than Minimal Risk
Category:	Expedited: 5
Comments/Conditions:	IRB waived requirement for informed consent and authorization. Form W is issued.

This Assurance, on file with the Department of Health and Human Services, covers this activity:

FWA No: 00004557
Expiration Date: April 14, 2020
IORG: 0000251

Before 12/24/2016 or within 25 business days of study closure, whichever is earlier, you are to submit a completed "FORM: Continuing Review (HRP-212)" and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 02/07/2017 approval of this protocol expires on that date.

If your research involves recombinant DNA molecules, human gene transfer, infectious agents, or biohazardous materials, please contact the Institutional Biosafety Committee to determine if a Biological Use Authorization is required.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

Jun Porter, MS, CCRC, CIP
Designated Reviewer
Institutional Review Board Administration
University of California, Davis
2921 Stockton Blvd., Suite 1400
Sacramento, CA 95817
916-703-9167

cc: Pamela Keach

Name and Title of Representative: Magdalena Cerdá
Name of the Organization: Department of Emergency Medicine UC Davis Medical Center
Mailing Address: 2315 Stockton Blvd, Sacramento CA, 95817
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I. Purpose for requesting data

The title of the project is "Prescription drug monitoring programs and opioid-related harm." Prescription drug monitoring programs (PDMPs), state-level databases to which pharmacy dispensers must report prescription information when certain medications are dispensed, have been advanced as tools to reduce the burden of disease associated with the prescription opioid epidemic.

This study proposes to use data from a diverse sample of U.S. states to empirically identify prescription drug monitoring program "best practices" that are related to the greatest reduction in prescription opioid overdose and to the least increase in heroin overdose over 21 years of study. This information will be available to states and to the national PDMP Center of Excellence to inform PDMP practices and clinical practice.

Specifically, this study proposes to compare the incidence of prescription opioid (PO) and heroin overdose from 1993 to 2014 across states pre- and post- activation of prescription drug monitoring programs (PDMPs). It also proposes to examine overdose pre- and post-change in specific PDMP characteristics, since states may have enacted a PDMP system at one point but then changed PDMP characteristics over time, so that the system increasingly adhered to "best practice" recommendations over time. We propose to focus on the years 1993-2014 to take advantage of the availability of pre- and post-PDMP enactment hospital discharge data in a range of urban and rural states in those years.

Our specific aims are:

1. To test the relation between implementation of specific "best practice" PDMP features and change in prescription opioid and heroin overdose

   H1: The incidence of prescription opioid overdose decreased with the introduction of "best practice" PDMP characteristics

   H2: The incidence of heroin overdose increased with the introduction of "best practice" PDMP characteristics

2. To test whether the relationship between implementation of PDMP "best practice" characteristics and prescription opioid and heroin overdose differed by medical need and socioeconomic characteristics of population groups

   H1: Populations living in areas with a higher concentration of groups with medical need for POs (e.g., higher discharge rates for arthritis and cancer, more manual labor industries) and

populations living in more affluent areas experienced a greater reduction in POD with the introduction of "best practice" PDMP characteristics

H2: Populations living in less affluent areas experienced a greater increase in HOD with the introduction of "best practice" PDMP characteristics than populations living in more affluent areas.

To test these aims, we will develop a typology of PDMP characteristics. Characteristics examined will include number of drug schedules reported; frequency of data reporting; proactive provision of data to authorized users; requirements for user training, registration, and data accessing; and interstate data sharing. We will assess compliance to PDMP "best practices" by determining the provider query rate for each state.

We will test the impact of variations in PDMP characteristics on rates of hospitalizations due to PO and heroin overdose across 24 U.S. states with available pre- and post-PDMP hospitalization data and heterogeneity in the year of PDMP operation, and among persons living in 13,512 zip code areas within those states across 1993-2014. We have already acquired data from 12 states through the Healthcare Cost and Utilization Project (HCUP), and are carrying out individual requests for states that do not release their data to HCUP.

In particular, we would like to request data from 1992-2014 hospital inpatient discharge data (with the 5-digit zip code variable). These data will allow us to analyze annual counts of opioid and heroin-related hospital discharges, localized by residential zip code, county, and state and to examine the impact that state-level PDMP characteristics have in local communities over time. Our study population includes all individuals admitted to community hospitals in 24 states, between 1993 and 2014.

Attachment #2 – Data Management Plan(s)

Contractor #1: Prevention Research Institute

Name: Paul Gruenewald Telephone: 510-486-1111 Organization: Prevention Research Center Fax: 510-644-0594
Address: 180 Grand Av. Ste. 1200 E-mail: paul@prev.org
Function: Scientific Director / Senior Research Scientist

Name: William Ponicki Telephone: 510-883-5713 Organization: Prevention Research Center Fax: 510-644-0594 Address: 180 Grand Av. Ste. 1200 E-mail: bponicki@prev.org
Oakland, CA 94612
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Name: Andrew Gaidus Telephone: 510-883-5760
Organization: Prevention Research Center Fax: 510-644-0594 Address: 180 Grand Av. Ste. 1200 E-mail: aguidus@prev.org
Function: Research Associate - GIS Specialist

Describe which data will be provided to this contractor and describe, in detail, the security measures that they propose to use, maintain and store the requested data.

- **System**
  Networked computer system protected from the viruses, malware, network intrusion, and unauthorized access threats by the latest version of Symantec Endpoint Protection. All computers and servers on this network are automatically updated with the latest operating system and application level patches. All staff are required to have unique logons to control access and can only access their own profile and folders to which they have been specifically granted access. Sensitive data will be excluded from network backups.

- **Hardware/Software**
  Discharge-specific raw data will be maintained on an encrypted removable hard drive kept separate from the local desktop computer and network. When not in use this removable hard drive will be stored in a locked room. The zip-code level count data will be maintained on a networked desktop computer on a private and secure network separated from the public internet.

- **Access Control**
  Network and workstation access is restricted to authorized users with unique logon. While not in use a computer is locked, with screen saver locks requiring password after 15 minutes of inactivity.

- **Physical Environment**
  The discharge-specific raw data will be maintained on an encrypted removable hard drive stored in a locked room. The zip-code level count data will be maintained on a local desktop computer located in a locked office. All data will be located in a suite protected by electronic access controls, within a building with access controls and 24 hour security.

- **Data Storage**
  The original patient-level data files will only be used to create annual zip-code level counts of both total hospitalizations and discharges with specific ICD-9 codes (e.g. opioid abuse, opioid poisoning, or other conditions that often lead to use of prescription opioid medications such as arthritis). The original patient-level data will be stored on an encrypted removable hard drive, which will be stored in a locked room when not in use. The zip code level files with patient count data will be stored on a password-protected workstation on a secure network as described above.

- **Encryption**
  Patient-level data files with individually-identifiable will be encrypted with a key length of at least 256 bits.