DUA Project #\_



State of California Department of Health Care Services



## **REVISIONS ONLY REQUEST APPLICATION** TO OBTAIN OR MAINTAIN PROTECTED DHCS DATA

This application is to be utilized to revise previously approved data use of confidential and protected data provided by the Department of Health Care Services (DHCS) for research or public health purposes. In addition to this form, requestors must also submit:

- A Data Description Table in Excel (highlighting the newly requested data)
- A copy of filled DUA (see VII for detailed instruction)
- A copy of the Committee for the Protection of Human Subjects (CPHS) revised approval and revised research protocol.
- I. Project Title:

Data Use Agreement Number:

- II. Name and contact information for Principal Investigator (PI)
  - a. Name (Last, First):
  - b. Title:
  - c. Institution:
  - d. Address:
  - e. E-mail:
  - f. Phone #:
  - g. Fax #:

Name and contact information for other contact person or subcontractors (if applicable)

- h. Name (Last, First):
- i. Title:
- j. Institution:
- k. Address:
- I. E-mail:
- m. Phone #:

III. Are you requesting any changes to your approved protocol, including use of additional data variables or years of data?
Yes 🗌 No 🗌
(If 'Yes," please specify and justify revisions and address whether revisions change subjects' risk level in the field below. Please attach copies of old protocol with tracked changes and clean copies of new protocol with original signatures from the PI and Responsible Official).
IV. Are you requesting a change in the PI?
Yes 🗌 No 🗌
( <i>If "Yes,"</i> please specify the previous and the new PI in the box below. Please also address any potential conflict of interest questions including description of financial or other relationships that could be perceived as affecting objective research and the interpretation and publication of findings. Please also submit the new PI's curriculum vitae.)
<ul> <li>V. Do you have any other requests for changes (such as substantial changes in the methodology)?</li> <li>Yes </li> <li>No </li> </ul>
(If yes, please provide details below).
VI. Is there a change in how you are using the data?
Yes 🗌 No 🗌
(If yes, please provide details below).
VII. Data Use Agreement (DUA): Starting in 2018, signatures on DUAs are now collected via DocuSign. Wet ink signatures are no longer required, but still accepted; however, signed and scanned copies are NOT valid for DUA. Please only fill in the grey areas on the word version of the DUA located on the DRC website and do not sign or initial the word version of the DUA.
<ul> <li>Application Checklist:</li> <li>A signed and scanned copy of this revised application;</li> <li>A copy of the old protocol with tracked changes and a clean copy of the new protocol with the original signatures from the PI and Responsible Official;</li> <li>A completed Data Description Table in Excel version (only if requesting new data);</li> <li>A filled out word version of the Data Use Agreement (Only if the information on the previous DUA is changed.);</li> <li>A copy of the Committee for the Protection of Human Subjects (CPHS) REVISED approval and REVISED research protocol.</li> </ul>

Application materials must be submitted electronically to <u>DHCSDRC@dhcs.ca.gov</u>. Signed hard copy of DUA can be mailed to the following address:

Department of Health Care Services Information Management Division, MS 0021 P.O. Box 997413 Sacramento, CA 95899-7413

Please Note: Prior to the release of any new DHCS protected data, a copy of the approval letter for the change from the Committee for the Protection of Human Subjects (CPHS) of the California Health and Human Services (CHHS) Agency must be submitted to the address above. The CPHS website is: <a href="http://www.oshpd.ca.gov/boards/cphs">www.oshpd.ca.gov/boards/cphs</a>

Signature of Principal Investigator: \_\_\_\_\_

Printed Name (Last, First):

Date:

Signature of the Responsible Official at your institution: \_\_\_\_\_

Printed Name of Responsible Official at your institution (Last, First):

Title:

Institution Name:

Phone #:

E-mail: