UNIVERSITY OF CALIFORNIA

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO

SANTA BARBARA • SANTA CRUZ

OFFICE OF THE VICE PRESIDENT – RESEARCH AND INNOVATION

OFFICE OF THE PRESIDENT
1111 Franklin Street, 11th Floor
Oakland, California 94607-5200

January 3, 2022

California Department of Justice
Justice Data and Investigative Services Bureau
Attn: Haylee James
P.O. Box 160447
Sacramento, CA 95816-0608
E-mail: CURESregulations@doj.ca.gov

RE: Department of Justice Notice of Modification to Text of Proposed Regulations regarding the Controlled Substance Utilization Review and Evaluation (CURES) at Title 11, Division 1, Chapter 8 Issued on December 15, 2021

Dear Ms. James:

I write on behalf of the University of California (UC) system with regard to the Notice of Modification to Text of Proposed Regulations specific to the Controlled Substance Utilization Review and Evaluation (CURES) at Title 11, Division 1, Chapter 8 issued by the Department of Justice (DOJ) on December 15, 2021.

The UC system has more than 800 research centers, institutes, laboratories, and programs that span 10 campuses, 6 medical schools, a Division of Agriculture and Natural Resources, and 3 affiliated U.S. Department of Energy national laboratories. UC has established an unparalleled reputation for research and innovation that contributes to the state and nation through discoveries and new technologies that improve health, quality of life, and public safety. With regard to research involving CURES data, UC conducts epidemiological and patient-oriented research utilizing healthcare records and other state-managed databases to assess the effectiveness of treatments for substance use disorders, examines clinical factors in substance abuse and treatment, and identifies predictors of opioid dose escalation and/or overdose involving prescribed medications. These efforts include multiple research projects conducted in collaboration with DOJ.

This letter serves to comment on both the proposed text and the document incorporated by reference in the Notice of Modification to Text of Proposed Regulations entitled DOJ Consent for Use of Personal Information from CURES, CURES 0001 (Orig. July 2021), hereafter referred to as "the DOJ Consent form". The DOJ proposed text at 828.6(c)(11)(H) provides that Identified Individual-Level Data may be accessed via Civil Code section 1798.24, subdivision (b) or Civil Code section 1798.24, subdivision (t). Under the discussion on access to the data via Civil Code section 1798.24, subdivision (b), DOJ requires the use of the above referenced DOJ Consent form. While UC believes that DOJ may have developed the consent form as a resource to its constituents, we are concerned about privacy risks it presents, in addition to barriers it creates when the form is used for research purposes. UC asks that DOJ specify within the regulatory text that the DOJ Consent form would not be used for accessing Identified Individual-Level Data for research purposes. More information is provided below:

I. General Comments on Use of the DOJ Consent Form

UC fully supports the fundamental need to ensure the privacy and security of identifiable data, particularly with respect to sensitive medical information, such as controlled substance use. We agree that it is important that state agencies adopt policies and practices to prevent unauthorized or unnecessary use or release of this information. However, we believe that the use of the DOJ Consent form does not necessarily achieve this goal. The form requires collecting personal information, such as all variations of an individual's name and address, as well as either a) copy of an identification card or b) notarized identity confirmation. The collection of this information is considerably more than what is required for typical patient or research consent, even for research on highly sensitive topics such as illicit drug use or other illegal activities. This not only places a burden on those who would consent to the use of their data, but also requires the collection of more information than is necessary to accomplish the intended purpose of a particular request for use of the data. As such, we believe that using the DOJ Consent form creates unnecessary privacy risks.

II. Comments Specific to the Use of the DOJ Consent Form for Research Purposes

The DOJ proposed text provides that Identified Individual-Level Data may be accessed via Civil Code section 1798.24, subdivision (b) **or** Civil Code section 1798.24, subdivision (t). Under the discussion on access to the data via subdivision (b) (see proposed text at 828.6(c)(11)(H)(1)), there is a requirement to use a specified DOJ Consent form. Most researchers accessing data would likely utilize access to Identified Individual-Level Data following 1798.24 subdivision (t) and seek review by the Committee for the Protection of Human Subjects or another applicable institutional review board.

Informed consent is an ethical and legal requirement for research involving human participants and is the cornerstone of the underlying federal regulations for the protection of human subjects (45 CFR 46). However, the proposed DOJ Consent form runs counter to the spirit and letter of 45 CFR 46 in several ways.

First, the DOJ Consent form is not consistent with commonly accepted best practices (encouraged by 45 CFR 46) that consent documents should be concise, focused, and easy to understand. The DOJ Consent form does not allow adequate space for description of the overall study, of which Individual level CURES data may be only one component. Thus, any researcher using the DOJ Consent form would have to use an additional consent form to adequately explain the study, increasing participant burden with no corresponding benefit. Moreover, the DOJ Consent form is filled with jargon and legalese that most participants would not understand. As just one example, the DOJ Consent form frequently uses the term "bona fide researcher" which has no meaning in everyday language and so would confuse most research participants.

Second, the DOJ Consent form places unnecessary burdens on participants and, paradoxically, increases risks for loss of patient privacy and data confidentiality by requiring notarized identity authorization or a copy of participants' photo identification. The requirement to notarize individual consent forms is far outside standard research practice. How would researchers even obtain notarization if, for example, they were recruiting patients in clinic, hospital, or other research settings? The proposed DOJ requirement of including a photocopied identification form (which in practice would likely be patient driver's licenses) increases risk to patient privacy by collecting additional sensitive information (e.g. driver's license number) that is not necessary for research studies with no corresponding benefit. Requiring a copy of a participant's driver's license reduces patient privacy and is analogous to, say, police officers requiring motorists to give their medical record number when motorists are stopped for a traffic violation.

Third, requiring a list of all permutations for patient information (first and last name, full address, date of

birth) is counterproductive because pharmacies manually maintain this information making it subject to human error and variations in the way the information is recorded, particularly for addresses and hyphenated names (e.g., CURES records often reverse patient last and middle names). The process for matching Identified Individual-Level Data from CURES should allow for broader searches that mirror how CURES is actually used clinically. For example, clinicians typically search for CURES identities using date of birth, last name, and either first name or first initial. In practice, clinicians never restrict searches by address because requiring an exact match on address would miss a large number of valid prescription records. For example, a search restricted to the street address "123 Main Street" would not match if pharmacies reported the address to CURES as 123 Main St."

Recommendation: UC strongly recommends the DOJ make clear that researchers accessing Identified Individual-Level Data pursuant to 1798.24 subdivision (t) do not need to use the DOJ Consent form. See underlined suggested language below:

> "2. To comply with Civil Code section 1798.24, subdivision (t), for purposes of this article, the Bona Fide Researcher must obtain formal approval for the use of Identified Individual-Level Data, in accordance with the requirements of Civil Code section 1798.24, subdivision (t), by the Committee for the Protection of Human Subjects for the California Health and Human Services Agency or the Bona Fide Researcher's institutional review board, if that institutional review board has a written agreement with the Committee for the Protection of Human Subjects for that institutional review board to provide the data security approvals required by Civil Code section 1798.24, subdivision (t). The Bona Fide Researcher requesting Identified Individual-Level Data are not required to use the Consent for Use of Personal Information from CURES Form (Orig. 07/2021) to comply with Civil Code section 1798.24, subdivision (t). The Bona Fide Researcher may first submit its application to the Department's Research Center. The Department's Research Center may provide written documentation to the Bona Fide Researcher to allow the Committee for the Protection of Human Subjects to review the Bona Fide Researcher's application. The Bona Fide Researcher must provide written verification to the Department's Research Center of formal approvals by the Committee for the Protection of Human Subjects or the Bona Fide Researcher's institutional review board, if operating under a written agreement under Civil Code section 1798.24, subdivision (t), for the request of Identified Individual-Level Data from CURES. The written verification must include the review and determination by the Committee for the Protection of Human Subjects or the Bona Fide Researcher's institutional review board, if operating under a written agreement under Civil Code section 1798.24, subdivision (t), that the data security approvals required by Civil Code section 1798.24, subdivision (t), have been satisfied"

We would like to thank you and your team for your diligent efforts in developing regulations to ensure the security of sensitive data concerning controlled substance use. The UC system looks forward to continuing its collaborations with the DOJ to pursue academic research beneficial to stakeholders within the State of California and beyond. We welcome any opportunity to discuss further the comments of this letter.

Sincerely,

Deborah Motton, Ph.D.
Executive Director
Research Policy Analysis and Coordination
University of California, Office of the President