

Data Use Agreement
Between CDPH and the County of Fresno

DATA USE AGREEMENT (DUA)
Between
THE CALIFORNIA DEPARTMENT OF PUBLIC HEALTH (CDPH)
and
THE COUNTY OF FRESNO

1. Parties

This DUA has been made and entered into by and between CDPH and the County of Fresno, Healthy Start Grantee (HS Grantee).

2. Service Overview

The HS Grantee is a grantee of the federal Maternal Child Health Bureau, Health Resources and Services Administration (HRSA) and has agreed to be part of a national Healthy Start evaluation to be conducted by HRSA. This DUA will establish protocols and restrictions for governing data information sharing to conduct a national evaluation of the Healthy Start program for the HS Grantee. The HS Grantee will seek the informed consent of HS Grantee participants to allow the HS Grantee to provide certain personally identifiable data (Linkage Variables) to CDPH. CDPH will receive from HS Grantee the Linkage Variables on selected 2017 Healthy Start participants who have consented to participate in the national Healthy Start evaluation. CDPH will use the Linkage Variables to link with information provided on the birth and infant death records associated with these Healthy Start participants. CDPH will then submit the linked data and de-identified annual birth data for the HS Grantee's county to HRSA to tabulate the data. HRSA will conduct their evaluation pursuant to approval by the California Committee for the Protection of Human Subjects and the California Vital Statistics Advisory Committee.

3. Legal Authorities

- A. The provisions of the California Health and Safety Code (HSC) sections 102230 and 102231 authorize this DUA.
- B. Pursuant to HSC section 102232, violation of HSC section 102231 or 102230 is a misdemeanor punishable by one year in jail and/or a fine of \$1,000 for each violation. Additionally, violation of the terms of this DUA or HSC section 102230 may be cause for denial of any further access to the data files maintained by CDPH.

4. Effect of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)

- A. CDPH and HS Grantee HIPAA Status:** CDPH is a “hybrid entity” for purposes of applicability of the federal regulations entitled “Standards for Privacy of Individually Identifiable Health Information” (Privacy Rule) (45 C.F.R. parts 160, 162, and 164) promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C. §§ 1320d - 1320d-8) (as amended by Subtitle D Privacy, of the Health Information Technology for Economic and Clinical Health (HITECH) Act (Pub. L. 111–5, 123 Stat. 265–66)). The Public Health Policy and Research Branch has not been designated by the CDPH as, and is not, one of the HIPAA-covered “health care components” of CDPH. (45 C.F.R. § 164.504(c)(3)(iii).) The legal basis for this determination is as follows:
1. The Public Health Policy and Research Branch is not a component of CDPH that would meet the definition of a covered entity or business associate if it were a separate legal entity. (45 C.F.R. §§ 160.105(a)(2)(iii)(D); 160.103 (definition of “covered entity”).) And,
 2. The HIPAA Privacy Rule creates a special rule for a subset of public health activities whereby HIPAA cannot preempt state law if, “[t]he provision of state law, including state procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.” (45 C.F.R. § 60.203(c) [HITECH Act, § 13421, sub. (a)].) [NOTE: See State laws and regulations in Legal Authorities].
- B. CDPH is a “Public Health Authority”:** CDPH is a “public health authority” as that term is defined in the Privacy Rule. (45 C.F.R. §§ 164.501; 164.512(b)(1)(i).)
- C. Linkage Variables Use and Disclosure Permitted by HIPAA:** To the extent a disclosure or use of Linkage Variables may also be considered a disclosure or use of “Protected Health Information” (PHI) of an individual, as that term is defined in part 160.103 of Title 45, Code of Federal Regulations, the following Privacy Rule provisions apply to permit such Linkage Variables disclosure and/or use by CDPH and HS Grantee, without the consent or authorization of the individual who is the subject of the PHI:
1. HIPAA cannot preempt state law if, “[t]he provision of state law, including state procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.” (45 C.F.R. § 60.203(c) [HITECH Act, § 13421, sub. (a)].) [NOTE: See state laws and regulations listed in Legal Authorities].

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2. A covered entity may disclose PHI to a “public health authority” carrying out public health activities authorized by law (45 C.F.R. § 164.512(b));
 3. A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law. (Title 45 C.F.R. §§ 164.502 (a)(1)(vii), 164.512(a)(1).) And,
 4. Other, non-public health-specific provisions of HIPAA may also provide the legal basis for all or specific Linkage Variables uses and disclosures.
- D. No HIPAA Business Associate Agreement or Relationship between CDPH and HS Grantee:** This Agreement and the relationship it memorializes between CDPH and HS Grantee do not constitute a business associate agreement or business associate relationship pursuant to Title 45, CFR, part 160.103 (definition of “business associate”). The basis for this determination is part 160.203(c) of Title 45 of the Code of Federal Regulations (see, also, [HITECH Act, § 13421, subdivision. (a)]). Accordingly, this Agreement is not intended to nor at any time shall result in or be interpreted or construed as to create a business associate relationship between CDPH and HS Grantee. By the execution of this Agreement, CDPH and HS Grantee expressly disclaim the existence of any business associate relationship.

5. Term of DUA

The term of this DUA is effective upon the date last signed and executed by the duly authorized representative of both parties, whichever is later, and will remain in effect through May 31, 2019.

6. Definitions

“Linkage Variables” means personally identifiable information identified in Exhibit A provided by the HS Grantee to CDPH in order to obtain linkage with vital records.

7. Project Representatives

A. The project representatives during the term of this DUA will be:

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, PUBLIC HEALTH POLICY AND RESEARCH BRANCH Ellen Badley, Chief, MHA Public Health Policy and Research Branch PO Box 997410, MS 5101 Sacramento, CA 95899-7410 Telephone: (916) 552-8095 E-mail: ellen.badley@cdph.ca.gov	COUNTY OF FRESNO Ah Vang, Health Educator Department of Public Health P.O. Box 11867 Telephone: (559) 600-3330 E-mail: ahvang@co.fresno.ca.us
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B. Direct all administrative inquiries to:

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, PUBLIC HEALTH POLICY AND RESEARCH BRANCH Leo Dyragos, Unit Chief Policy and Analysis Unit PO Box 997410, MS 5101 Sacramento, CA 95899-7410 Telephone: (916) 621-1545 E-mail: leo.dyragos@cdph.ca.gov	COUNTY OF FRESNO Aphivanh Xayavath, Staff Analyst Department of Public Health P.O. Box 11867 Telephone: (559) 600-3330 E-mail: axayavath@co.fresno.ca.us
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C. Direct all data delivery and information technology inquiries to:

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH	COUNTY OF FRESNO
John Marinko, Contractor PO Box 997410, MS 5101 Sacramento, CA 95899-7410 Telephone: (916) 449-5174 E-mail: John.Marinko@cdph.ca.gov	Rose Mary Rahn, Division Manager Department of Public Health P.O. Box 11867 Telephone: (559) 600-3330 E-mail: rrahn@co.fresno.ca.us

D. Direct all privacy and security inquiries to:

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, INFORMATION SECURITY OFFICE	COUNTY OF FRESNO
Charles Lano, Chief Information Security Officer PO Box 997377, MS 6302 Sacramento, CA 95899-7413 Telephone: (855) 500-0016 E-mail: Charles.Lano@cdph.ca.gov	Privacy: David Pomaville, Director Public Health P.O. Box 11867 Fresno, CA 93775 Telephone: (559) 600-6405 E-mail: dpomaville@fresno.ca.us Security: Robert W. Bash, Director Internal Services/Chief Information Officer 333 W. Pontiac Way Clovis, CA 93612 Telephone: (559) 600-5800 E-mail: rbash@FresnoCounty.gov

8. Responsibilities of the Parties

A. CDPH agrees to:

1. Receive the Linkage Variables, use them solely for the purposes expressly authorized in the Service Overview and not share that data with any other agency during the duration of this DUA. No other use is granted under this DUA, and data will not be used to approve or deny any service.
2. Protect data files and not sell, release, or otherwise transfer any portion of the data files unless expressly permitted in this DUA.
3. Ensure appropriate protections are implemented for administrative, physical, and technical safeguards that will protect the confidentiality, integrity, and availability of the data files.

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4. Ensure all precautions are in place for continuous security of all computerized data systems containing the data files.
5. Transmit data files to HRSA, and no other entity, via a secure, industry standard process.
6. Consistent with CDPH's records retention requirements, destroy Linkage Variables received from HS Grantee at the conclusion of the national Healthy Start evaluation.

B. HS Grantee agrees to:

1. By April 10, 2018, or as soon as possible thereafter, provide Linkage Variables to CDPH for:
 - a) Any pregnant woman served in calendar year 2017 with informed consent, including any served in 2016 with a known or expected delivery date in 2017.
 - b) Any postpartum woman served in calendar year 2017 with informed consent, who delivered in 2017 or beyond. This group will serve as an important internal comparison group.
2. Capture the Linkage Variables in Excel spreadsheet format, as described in Exhibit B, and send via secure email such that the information contained in the email is encrypted, and is available to the project representatives.

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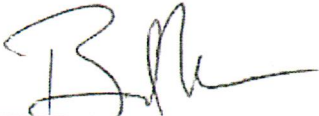
9. **Effective Date and Signature**

This DUA will be effective upon the signatures of CDPH and HS Grantee.

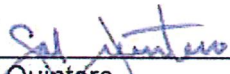
Wherefore, in witness of the covenants set forth above on the attached pages, the parties have affixed their signatures hereto:

California Department of Public Health:

County of Fresno:



Brandon Nunes
Chief Deputy Director of Operations

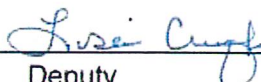


Sal Quintero
Chairperson of the Board of Supervisors
of the County of Fresno

Date: 8/23/18

Date: July 10, 2018

ATTEST:
Bernice E. Seidel
Clerk of the Board of Supervisors
County of Fresno, State of California

By: 

Deputy

EXHIBIT A

Instructions for HS Grantee to collect Individual Identifiers (Linkage Variables)

Collect as many individual identifiers as possible from the list of participants below (**bold** are required):

- 1) Any pregnant woman served in calendar year 2017 with informed consent, including any served in 2016 with a known or expected delivery date in 2017.
- 2) Any postpartum woman served in calendar year 2017 with informed consent who delivered in 2017 or beyond. This group will serve as an important internal comparison group.

The greater the detail that is collected, the greater the likelihood of successful linkage to vital records.

Individual Identifiers (Linkage Variables)

- **Mother's name* in separate fields for:**
 - First
 - Middle
 - Last
 - Maiden
- **Mother's date of birth**
- **Mother's Unique Client ID #** that can be used to anonymously identify the HS participant and subsequently link back to any client-level information (e.g., 3Ps) that is provided to HRSA
- **Mother's address at time of delivery**
 - Street number
 - Street name
 - City
 - ZIP code
 - County
- **Infant's date of birth*** (or expected month, day and year of delivery if unknown)
- **Infant's name *** in separate fields for:
 - First
 - Last

Bold = required elements

*May not be available if participant is lost to follow-up (e.g., moves, stops participating, etc.) or has not yet delivered; linkage will be attempted regardless of the number of available individual identifiers.

EXHIBIT B
County of Fresno Linkage Variables

[illegible]

Delivery Schedule	
Linkage Variables	4/10/2018, or as soon as possible thereafter