CENTER FOR DATA INSIGHTS AND INNOVATION
CALIFORNIA HEALTH & HUMAN SERVICES AGENCY

View xForm - Project Application v6

This form is for new projects that have not been previously approved by CPHS.

Data entry
- Submitted 01/07/2026 7:12 PM ET by Maryam Cheraghi, BA

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

February 2026 cycle.

_____New HSC Project-February 2026_____

01/02/2026 • Sussan Atifeh • Internal

Researchers from UCI have submitted this application to request approval for a project with human subjects contacts that is aimed to recruit families and then investigate how children's executive functions and memory develop, and how parenting and cultural practices influence that development.

They Plan to request California birth and death records solely to obtain parent names and mailing addresses so they can send recruitment letters inviting families to participate. Parents who receive the letter may voluntarily contact the research team by phone, email, or an online form to enroll their child. Once enrolled under UCI's IRB-approved protocol, children will complete age-appropriate behavioral and cognitive tasks like game-like executive-function activities, working-memory assessments, and surveys, while some parents may also complete interviews, questionnaires, or cognitive tasks. No information from the birth or death records will be used in the research itself; the state data are used only for recruitment, and all study activities occur only with families who self-initiate contact and consent to participate. The study is already approved by the UCI IRB.

• Data-Source Department:
CDPH/VSAC
No LOS yet—Only a Placeholder
****

• PROJECT SITE
University of California, Irvine (UCI)—A DSL from UCI is attached.

• FUNDING
Yes—University funded

• End-Product:
The expected end product is the sharing of results from the associated study through research reports, journal articles, and conferences.

• Linkage:
No

01/02/2026 • Sussan Atifeh • Internal

Dear Researchers: Please check all pages of the application (scroll down to see the entire page), address the comment(s), and resubmit the application. Thanks,

01/02/2026 • Sussan Atifeh • *Not* Internal

If personnel are not found by their email address while trying to complete the following questions, you can add them in the system with the link below. Click on the "New Contact Form" and complete it. Within a few minutes of completing the form, you will receive an email notifying you of the availability of the new contact. You should then be able to add them in the subsequent questions.

User had the option to start a different form here.

PRINCIPAL INVESTIGATOR (PI)

Enter the Principal Investigator's email address.

Lindsey Richland, PhD

Email: l.richland@uci.edu **Business:** (949) 824-7927

Choose the institution with which the PI is affiliated (not the location at which the research is being conducted).

University of California, Irvine

Enter the city in which the PI's institution is located.

Irvine

Enter the state in which the PI's institution is located.

Start typing in the state name to select the name from the list.

California

Attach a copy of the PI's Curriculum Vitae.

lindseyrichland_cv_92024.pdf PI Curriculum Vitae

Deleted Attachments: 1 (Most Recent: lindseyrichland_cv_92024.pdf on 01/04/2026 10:31 PM ET)

CO-PRINCIPAL INVESTIGATOR (CO-PI)

Enter the Co-PI's email address by clicking on the "Add Contact" button.

If there are multiple co-principal investigators, repeat this action for all Co-PIs. If there are no Co-PIs for this project, skip this question.

No answer provided.

ADMINISTRATIVE CONTACT

Enter the email address(es) for the administrative contact(s). If you are the administrative contact, enter your email address, and enter anyone else you want listed as an administrative contact.

Maryam Cheraghi, BA

Email: cheraghm@uci.edu **Business:** (949) 315-8454

RESPONSIBLE OFFICIAL (RO)

Enter the RO's email address.

*The RO **cannot** be the same person as the PI or Co-PI. The RO must have supervisory authority, in the administrative structure of the institution, over the PI.*

Julie Washington, PhD

Email: julieaw@uci.edu **Business:** (949) 824-7578

OTHER RESEARCH STAFF

Enter the email address for any other research staff by clicking the "Add Contact" button.

Understanding that this request is for a database and not a specific study - it is still unclear who is involved with the database versus a study that would use the database contact information. In example consent forms attached there are two PIs not listed in this research staff section. It is unclear who would have access to these data.

01/20/2026 • Jonni Johnson, PhD • Internal

Repeat this action for all other research staff not previously provided on this screen that should receive notifications about this project. If there are no additional research staff, skip this question.

Ella Rose, BA

Email: ellalr@uci.edu **Business:** (530) 601-0633

Check for PI same as RO (internal only question) *(Internal)*

False

Project Information

SUBMITTER

Application completed by:

Maryam Cheraghi, BA

Email: cheraghm@uci.edu **Business:** (949) 315-8454

PREVIOUSLY APPROVED EXEMPTION

Is there a previously-approved exemption from CPHS for this project?

No

PROJECT TITLE

Enter the project title (please capitalize each word in your title).

UCI Child Development Study

PROJECT SITE

Indicate the primary site at which the research will be conducted.

University of California, Irvine

STUDY PROCEDURES

Indicate the study procedures involved in this research. Check all that apply.

Since you plan to use State data for conducting this study, please select "Data Registry" in this section (as well as all other relevant options) and please attach all lists of requested variables (using descriptive names) by attaching the formal data dictionaries in the "DATABASE DETAILS" section.
In the attached list(s) you need to provide a brief explanation to justify requesting each variable and to show the use of the variables. Thanks.

• If you do not have access to the formal data dictionaries, you can create a Word or Excel document to list all the variables. Include three columns:
1. Name of Variables: List the requested variables.
2. Justification: Provide a brief explanation justifying the request for each variable. If the same justification applies to a group of variables, feel free to copy and paste it. Reviewers typically require this to ensure compliance with the Information Practices Act, which mandates that only the minimum necessary data be requested for the study.
3. Usage of Variables: Explain how each variable will be used.

• If you are using any publicly available data sets, please provide a separate list of the variables that will be used from public records and explain their relevance to the study.

Also, please in the "STATE DEPARTMENT DATA/SPECIMENS" section (at the bottom of the 3rd page of the application), Choose the department(s) from which you are requesting data and/or specimens (in the right column) and provide the formal name of the requested database or specimen registry (in the left column).

Thanks.

01/02/2026 • Sussan Atifeh • *Not* Internal • Resolved

Data Registry
Recruitment-Participant

TYPE OF RESEARCH REQUEST

Indicate which of the following applies to this research. Check all that apply.

If this project is involved with any contacts with human subjects and you use state data to contact subjects, please select "Common Rule/Human Subjects."

01/02/2026 • Sussan Atifeh • *Not* Internal • Resolved

*Death Data Only refers to health-related studies requesting existing mortality data from **within** the California Human Health Services Agency (CHHSA)*

*SB-13 (Information Practices Act) refers to health-related studies requesting existing data from **outside** the CHHSA (e.g. California Department of Corrections and Rehabilitation [CDCR], California Department of Education [CDE], etc.) **OR** studies requesting data **within** the CHHSA that are not state funded or involving state staff.*

Common Rule/Human Subjects refers to health-related studies that involve direct or indirect interaction with human subjects (e.g. recruitment, interviews, etc.)

*Common Rule Only refers to health-related studies requesting existing data from **within** the CHHSA (e.g. Office of Statewide Health Planning and Development [OSHPD], California Department of Public Health [CDPH], etc)*

Common rule/Human subjects

PROJECT TYPE DETAILS

Indicate which, if any, apply to this research. Check all that apply.

Are you requesting approval for "Non-English Translations" of the recruitment materials in this initial submission? If no, please de-select ""Non-English Translation Required" in this section.
If this study includes Spanish Translations, you have two options for submitting the Spanish materials:
1. Include them in the initial submission: If you expect to finalize the English versions and complete the Spanish translations soon, you may include a note in your application stating that "the Spanish materials will be submitted after the English versions are finalized and approved." This allows the committee to review both sets as part of the initial submission.

2. Submit them later via an amendment: If the Spanish translations won't be ready in time and you're concerned about delaying the approval of your initial submission, you may choose to submit them later through an amendment. In this case:
o De-select the "Non-English translations required" option under the "Project Type Details" section (page 2) of the initial application.
o Once the initial submission is approved and you've received the approval letter, you can submit an amendment specifically to request approval for the Spanish materials.

01/02/2026 • Sussan Atifeh • *Not* Internal • Resolved

Researchers: If you are not requesting CPHS to approve "Informed Consent Waiver" for this project, please de-select it the next time that the application is in data entry.

01/02/2026 • Sussan Atifeh • *Not* Internal

note for self- waiver is potentially for child assent, not parental consent

01/20/2026 • Jonni Johnson, PhD • Internal

If the research does not involve any of following, choose "None of the above."

Minimal Risk
Non-English translation required
Informed Consent Waiver

VULNERABLE POPULATIONS

Indicate which vulnerable populations, if any, will be involved with this research. Check all that apply.

If vulnerable populations are not part of the research, choose "Not applicable."
Note regarding minors: in the United States, a minor is under 18 years of age. If research is conducted outside the United States, a minor is under the age of majority in the countries where research is to be conducted.

Minors

Please click the link below to fill out the supplement involving children. After you've finished the form, you will need to save it locally and then attach in the space below.

Link to Children Supplemental Form

CHHS checklist for research involving children 2025.pdf Children Supplemental Form

Deleted Attachments: 1 (Most Recent: CHHS checklist for research involving children 2025.pdf on 01/04/2026 10:31 PM ET)

FUNDING

Is this research funded?

> Since you mentioned in this section that the project is University Funded, please attach a copy of the project's budget in the "Budget" section of this application (last page).
>
> 01/02/2026 • Sussan Atifeh • *Not* Internal • Resolved

Yes

Indicate the funding source for this project.
University funded

EXPEDITED REVIEW CONSIDERATION

Please check the criteria below that you think your project meets to qualify for an expedited review. If none of these expedited criteria are appropriate for your project, choose 'not applicable'; your protocol will be reviewed by the full committee. Note that CPHS will make the final determination of whether the project meets the criteria for expedited review.

> If this project involves any kind of contacts with human subjects, it is not eligible for an expedited review and should be scheduled for a full board review in the next CPHS full board meeting (to be held on 2/6/2026). Please select "Not Applicable" if this project has any human subjects contacts components.
>
> 01/02/2026 • Sussan Atifeh • *Not* Internal • Resolved

Protected Health Information/Personally Identifiable Data (PHI/PID) is defined as information in any format that identifies the individual, including demographic information collected from an individual that can reasonably be used to identify the individual. Additionally, PHI is information created or received by a healthcare provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, including any of the 18 HIPAA identifiers.

Note: Please be aware that individual participants may be identifiable by combining other items in the data even when none of the 18 HIPAA identifiers are present. Thus, a study may still contain PID even after removing or never acquiring the identifiers, and the investigator may still need to provide complete answers for the data security questions in the protocol.

***The Departments within the California Health and Human Services Agency (CHHSA) are: Aging, Alcohol and Drug Programs, Child Support Services, Community Services and Development, Developmental Services, Emergency Medical Services Authority, Health Care Services, Mental Health, Public Health, Rehabilitation, Social Services and Statewide Health Planning and Development.*

Not applicable

ANTICIPATED PROJECT START DATE

Projects cannot begin before they have been reviewed. The earliest possible start date is always the date of the next public meeting at which the project will be heard.

> Projects cannot begin before they have been reviewed. The earliest possible start date is always the date of the next public meeting at which the project will be heard. Please select 2/6/2026 or a date following this date within a few weeks.
>
> 01/02/2026 • Sussan Atifeh • *Not* Internal • Resolved

For a list of public meeting dates, see the CPHS website

02/06/2026

ANTICIPATED PROJECT END DATE

12/31/2029

Project Details

PURPOSE

Include a brief statement, less than 500 words, describing the research project. Be sure to address the background for the project, including relevant literature, the major research questions to be addressed, and the expected end product (e.g., article, report or other publications). Include the location(s) where the project will take place. The summary should be understandable to the general public.

Please ensure you have defined all acronyms upon their first use in each section of the application.

01/02/2026 • Sussan Atifeh • *Not* Internal • Resolved

Please briefly describe the expected end product(s) of this project—for example, a research report, journal article, thesis or dissertation, webinar or presentation, policy brief, recommendations for practice or policy, pilot program, or other relevant outputs.

01/02/2026 • Sussan Atifeh • *Not* Internal • Resolved

Note for Me: OK reading further in - this is a data application to create a database. It is not for a specific study per se but to create and retain information in a database that is kept by UCI to contact people as they become eligible. It does not specifically state that that is what they are doing but going to the links provided that is what it is.

01/20/2026 • Jonni Johnson, PhD • Internal

This project is a series of behavioral studies that investigate children's development of cognitive and social skills. This research builds on prior literature demonstrating that executive functions (EFs) and memory play a central role in children's learning, self-regulation, and long-term developmental outcomes. The study may benefit society by informing developmentally appropriate strategies for supporting young children's thinking and learning. The research examines important cognitive and behavioral child development constructs, including the development of executive functions and memory, as well as the impact of parent and cultural practices. One major research question addressed by this project is whether higher executive functions are trained primarily through activities that require high cognitive control and adherence to adult-designed task demands. A second research question examines whether children who engage in complex, meaningful tasks that allow them an essential role in their community show more seamless transfer of executive functions across development and throughout the lifespan. This re-interpretation of executive function training may allow policies and interventions to capitalize on assets already present in low-income U.S. communities, making them more sustainable and effective. To examine these questions, children who enroll in the study will complete a series of age-appropriate, game-like tasks and surveys designed to assess executive functions, working memory, and related cognitive skills. The research study itself takes place at the University of California, Irvine (UCI) and is conducted under a separate, approved UCI IRB protocol. The immediate purpose of this application is limited to recruitment. Birth and death data requested through this application will not be used in the research and will be used solely to mail recruitment letters to parents who may be interested in enrolling their child in the study. Parents who choose to participate will provide contact information for enrollment and may also opt to be contacted about future studies approved by UCI's IRB. The use of these recruitment efforts will allow the research team to reach a larger and more diverse group of families across demographic and language backgrounds, increasing the relevance of the findings to California's children. The expected end product is the sharing of results from the associated study through research reports, journal articles, and conferences.

MAJOR RESEARCH QUESTION

What is the major research question to be addressed in this project?

This project requests data for recruitment only, not for research purposes. Parents must contact us in order to be signed up for the study. No birth or death record data will be used in the study.

The study examine the development of executive functions and memory, and the impact of parent and cultural practices. Secondly, this study examines the assumption that higher EFs are trained primarily through increasing children's time spent on activities that require high cognitive control and adherence to adult-designed task demands.

STUDY PROCEDURES

Describe in detail all procedures for this research. Do not attach grant applications or similar documents. Information in this application must be sufficient to fully explain the procedures without such documents

Recruitment is an integral part of the research process. If birth and death data are being accessed to identify participants for a study, contact them to participate, have them read/sign consents, etc., then that use is considered research-related under CPHS guidelines and federal regulations. Recruitment is a research activity, and the sections of procedures and methodologies need to include all information, specifically materials to be used, of the research activities.

01/20/2026 • Jonni Johnson, PhD • Internal

Please describe in detail what the procedure looks like as well as the linkage procedure and method for contacting parents.

01/20/2026 • Jonni Johnson, PhD • Internal

Birth and death data requested will not be used in the research study, it will only be used for recruitment purposes. The following methods (approved by UCI's IRB) are being utilized to recruit parents: flyers, online advertisements-including social media, letters of emails, phone calls, group or class presentations. We are now requesting to receive CA birth and death records, after which we will recruit via a mailing of recruitment letters. The letter will introduce the UCI Child Development Study and explain to parents how they can sign up, if they choose to do so. Parents who receive our mailed recruitment letter will be invited to sign up for a study appropriate to their child's age and population. In order to do so, they must sign up themselves online, email the linked UCI email, or call the linked UCI phone number to provide their contact information.

If parents contact us they can voluntarily provide their contact information to be signed up for the study. If so, children will complete a series of gamelike tasks and surveys that are appropriate for their age range and population. For example, children up to age 5 may complete the Three
Scrambled Boxes task (Wiebe et al., 2010) which involves children searching for figurines hidden in boxes, while children ages 5-13 may complete the Digit Span task (Blackburn & Benton 1957) which involves saying back a list of numbers that have been give to them, to assess working memory. Some parents may be asked to complete interviews (e.g., about their children), questionnaires/surveys, or cognitive tasks (e.g., working memory tasks like the digit span) to examine how these variables relate to children's development. Birth and death data requested will not be used directly in the research study, data will only be used for recruitment purposes.

Please upload here any tables or charts related to your study procedures and any materials (such as surveys or interview questions) that will be presented to participants.
No answer provided.

RECORDING

Will audio or video recording occur?

No

DECEPTION

Will deception be used in this study?

No

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY (CHHSA) DEPARTMENTS LIST

Indicate any of the following CHHSA department(s)' involvement in providing research staff, funding and/or patients from State mental hospitals for this project.

Not applicable

STATE DEPARTMENT DATA/SPECIMENS

Choose the department(s) from which you are requesting data and/or specimens and provide the formal name of the database or specimen registry. After you have selected the department from the drop down and entered the formal name of the database or specimen registry, click 'add' and repeat to add additional data and/or specimens if applicable.

Agency	Provide the formal name of the data base or specimen registry.
California Department of Public Health	Vital Statistics

Study Population

POPULATION DESCRIPTION

Provide a full description of how human subjects will be involved in the research. Address characteristics of subjects such as: age; sex; ethnicity; and number of participants. Include requested participant number.

Human subjects are involved in this. Please provide the description as well as inclusion/exclusion criteria and anticipated participant number for the study.
01/20/2026 • Jonni Johnson, PhD • Internal

What is the previously approved study protocol referenced here?
01/20/2026 • Jonni Johnson, PhD • Internal

Human subjects will not be involved in research directly through our data request. We will be recruiting from these records, sending a mailer to all parents. We are requesting all records quarterly from the California Department of Public Health. All variables, years, and justifications are included in the attachments in the next section.

We are requesting dynamic birth and death data 2025-2029 (In addition to the data that was previously approved and distributed to us from birth years 2008-2023 and static data from 2024). We are requesting contact information to recruit these families who are eligible for our study age range of 0-13.

DATABASE DETAILS

List the database(s) to be used and the time period(s) being requested. This may include requests for future data that is not available at this time.

This list of variables is extremely narrow to enable a data linkage process of identifying deceased children - the only overlapping fields between the two sources are child's first name, child's last name, and child dob. This will not be enough for researchers to adequately link and determine when a child has passed and risks contacting parents of deceased children or not contacting parents who would otherwise be eligible for participation. This will likely give you one-to-many data linkage scenarios where you would be guessing or simply not contacting (e.g., cultural variations in Spanish naming conventions may have the same first name but different middle names - middle name of child and parents would assist with data linkage).

Additionally, why are parents info for death not also included as potential match to identify deceased children?

Are you also looking for deceased parents (i.e., mothers who die in child birth or thereafter), are there plans to screen for this possibility to not contact bereaved spouse?

01/20/2026 • Jonni Johnson, PhD • Internal

List the variables being requested, including a brief description of each variable.
Justify the need for each variable and for the quantity of data being requested.
You may also attach a list of variables on the next question.

Also address if participants will be involved in any other studies.

We are requesting dynamic and static birth and death records for recruitment purposes only. Names, justification, and usage of variables are listed in the attachments below.

If you have a list of variables with the details requested in the above question, attach that here. If you provided all details on the database in the question above, skip this question.

BSMF_Request_DD_Richland_12.8.25 (1).xlsx	List of Variables
CCBF_Request_DD_Richland_12.8.25 (4).xlsx	List of Variables
CCDF_Request_DD_Richland_12.8.25.xlsx	List of Variables

RATIONALE

What is the rationale for studying the requested group(s) of participants?

The use of these recruitment efforts will ensure that this research will develop insights that are relevant to improving the lives of California's children broadly because it will allow us to conduct research with both a greater number and a more broad set of families from different demographic and language backgrounds than we would have been able to contact otherwise.

RECRUITMENT DETAILS

Describe how potential subjects will be identified for recruitment. Examples include: class rosters; group membership; individuals answering an advertisement; organization position titles (e.g., presidents, web designers, etc.). How will potential participants learn about the research and how will they be recruited (e.g., flyer, email, web posting, telephone, etc.)?

> The data requested are mailing information from birth certs which parents may move. Please supply statement as to how the research team has identified the recipient to be contacted as a potential participant.
>
> How many times are you reaching out to send the mailer? Is it per child? e.g., if a mom has 3 children over the course of 6 years - is she being contacted per child? How is this family unit linkage tracked?
>
> 01/20/2026 • Jonni Johnson, PhD • Internal

Important to remember: subjects cannot be contacted before IRB approval.

The immediate purpose of this application is to mail recruitment letters to parents who may be interested in joining the UCI Child Development Study. We will invite parents to sign up for developmental research that is being conducted at UCI. Thus, the CA birth records requested by this application will be used solely for recruitment purposes (not for research). We are requesting CA birth and death records in order to recruit parents via a mailing to the addresses received. Parents can provide their contact information so we can contact them when their children meet the enrollment criteria for the study being conducted. The only form of recruitment that will be used in association with the birth records received is a mailed recruitment letter (attached below).

Attach copies of all recruitment materials.

Recruitment Letter Child Development Study 1.7.26.pdf	Recruitment Materials
SPANISH Recruitment Letter Child Development Study 1.7.26.pdf	Recruitment Materials

SCREENING

Will subjects be screened prior to entry into the research?

> On your website for parents to sign up you have the upper limit as 18 years old not 13. Is this a typo? If not, then please clarify the differences.
>
> 01/20/2026 • Jonni Johnson, PhD • Internal

Yes

Please address the criteria for exclusion and inclusion in the research during the screening process. Provide reasons for not including women or minorities. Provide justification for including vulnerable populations such as children or prisoners. Please also provide a statement regarding what will happen to the information collected about the individual should they not enter into the study.

Parents and their children are eligible to be added to this study if they are a parent or legal guardian of a child from 0-13 years of age. Children's cognitive and social-emotional skills develop over the lifespan. Thus, we are specifically recruiting children 0-13, but no other criterion is used for eligibility.

COMPENSATION

Will subjects be compensated for participating in the study?

Yes

Compensation type
Gift card
Cash

Explain the amount and schedule of compensation that will be paid for participation in the study. Include provisions for prorating payment. The amount should not be coercive.
Participants will receive varying amounts and schedules of compensation depending on the child's age and activities completed. All amounts are approved by UC Irvine's IRB.

STUDY DURATION

Estimate the probable duration of the entire study. This estimate should include the total time each subject is to be involved and the duration of each data collection about the subject.

It is unclear the number of times someone is being contacted, whether it is per child, and why it needs to be repeated. Please explain why someone would be contacted multiple times if they never reach back out to sign up for your database?

01/20/2026 • Jonni Johnson, PhD • Internal

E.G., This is a two-year study. Participants will be interviewed three times per year; each interview will last approximately two hours. Total approximate time commitment for participants is 12 hours.

This project is a series of behavioral studies that investigate children's development of cognitive and social skills. Thus, different age ranges may be tested across various times spanning across multiple years, so recruitment mailings may take place at varying times. Recruitment mailings may take place multiple times per year, through the end of data access (requested until 2029). The only contact we will make to individuals whose data we receive through this request is the recruitment letter that we will mail to their address to invite them to join the study. From that point, it is up to individual parents to reach out to us to express interest in joining the study, at which point we will inform the parent about study details specific to their child's age range.

Risks and Benefits

RISK DESCRIPTION

Provide a description of possible risks to participants: physical, psychological, social, economic, loss of data security, and/or loss of confidentiality. Describe and justify whether the research is minimal risk or greater than minimal risk.

Please provide a clear explanation of the safeguards in place to minimize that risk of breaching confidentiality.

01/02/2026 • Sussan Atifeh • *Not* Internal • Resolved

With the variables requested, you may be contacting bereaved families - either those who have lost a spouse/child and your linkage process (not described) will not catch all of these. There is psychological risk associated with this - what is the plan to avoid this and/or respond if this occurs?

01/20/2026 • Jonni Johnson, PhD • Internal

The risks posed to the individuals who choose to be included in the study are minimal and do not differ from those encountered in daily life outside the laboratory. That is, the risks associated with inclusion do not differ from those associated with other events outside the laboratory in which adults are asked to provide participant-identifiable information. The only possible risk is a breach of confidentiality, such that individuals who are interested in being contacted about participating in research with their children will be asked to share participant-identifiable information about their children and themselves. If parents sign up for the study, other possible risks include becoming bored or tired, which is no greater risk than what participants encounter in daily life. Multiple safeguards are in place to minimize the risk of a breach of confidentiality. Access to participant-identifiable data (PID) will be limited to authorized research staff who have completed required CITI human subjects training and UC Cyber Security Awareness Fundamentals training. All staff with access to PID are documented on the UCI IRB–mandated study team tracking log and are required to sign confidentiality agreements. Physical records will be stored in a locked room with restricted access. Electronic data will be stored on an encrypted USB drive, accessible only to authorized study personnel. These measures are designed to protect participant confidentiality and prevent unauthorized access to identifiable information.

MEDICAL SERVICE RISKS

Describe how medical services will be provided if subjects suffer adverse mental or physical effects as result of research activity. If no services provided, state that clearly.

Not applicable.

INTERNATIONAL RESEARCH

Will this research occur outside of the United States or U.S. territories?

Check with client to see if they consider territories to be outside the U.S. or not, as this can vary between institutions.

No

LESS RISKY METHODS

Describe any less risky methods and why they are not being used.

Study is already minimal risk, there are no less risky methods.

BENEFITS

Describe the benefits, if any, to the subjects or to society that will be realized as a result of this project. Discuss the benefits that may accrue directly to the subjects as well as to society. If there is no direct benefit anticipated for the subjects, state that clearly.

There is no direct benefit anticipated for the participant. For society, recruiting participants across California would aid in reaching significantly more diverse families than would be accessible through routes that are currently more accessible such as conducting research at the campus childcare settings. The use of these recruitment efforts will likely allow us to reach both a greater number of families as well as families of different demographics than we would have been able to contact otherwise. The benefit of this would be more community relevant information about how to best support youth development and educational outcomes.

JUSTIFICATION OF RISKS

Explain why study risks are reasonable in relation to the potential benefits to subjects and to society.

Possible risks are no greater than what they encounter in daily life but there is opportunity to benefit communities and support youth development and educational outcomes.

Adminstrative Safeguards

PERSONALLY IDENTIFIABLE DATA (PID) INSTRUCTIONS

Protected Health Information/Personally Identifiable Data (PHI/PID) is defined as information in any format that identifies the individual, including demographic information collected from an individual that can reasonably be used to identify the individual. Additionally, PHI is information created or received by a healthcare provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, including any of the 18 HIPAA identifiers.

Note: Please be aware that individual participants may be identifiable by combining other items in the data even when none of the 18 HIPAA identifiers are present. Thus, a study may still contain PID even after removing or never acquiring the identifiers, and the investigator may still need to provide complete answers for the data security questions in the protocol.

If the researcher demonstrates that he or she is unable to comply with any of the requirements below, he or she may request an exception from these requirements. The researcher should indicate any measures that will be taken to address this requirement. The exception request should be made in the text box of the corresponding requirement. An exception will only be granted if the researcher can demonstrate that adequate alternative measures have been taken to minimize risks so as to justify the exception.

HIPAA IDENTIFIERS

Please identify which HIPAA Identifiers you plan to request as part of your submission.

Name
Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)
All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)

TRAINING PROCEDURES

Describe the procedures for training all research staff who have access to PID on privacy and security. Indicate if staff are required to sign a confidentiality statement related to general use, security, and privacy.

Research staff who have access to PID through this data request will have completed the CITI training and UC Cyber Security Awareness Fundamentals. They are tracked on the study team tracking log mandated by the UCI IRB and will be required to sign a confidentiality statement.

STAFF VETTING PROCEDURES

Describe procedures, either background check or thorough reference check, for vetting staff who will have access to PID.

Staff will be subject to a background check through live scan OR a thorough reference of at least three references per staff member.

SUPPORT LETTER

Obtain and submit a department support/data release letter.

To avoid confusion, please delete all other documents from this section and upload them only in their appropriate locations. In this section, you should include only the data request application you submitted to VSAC as a temporary placeholder until you receive the official Support Letter from CDPH/VSAC. Once the Support Letter is issued, please upload it here.

Additionally, please remove the 2020 support letter, as it pertains to a different project with a different title.

At this stage, the only file that should remain in this section is "CDPH Continuing Research Application Form-2025-12-23-14-05.pdf." For clarity, please rename this file to "VSAC Data Request Application – Placeholder."

01/02/2026 • Sussan Atifeh • *Not* Internal • Resolved

This is a statement from the state agency or department you are receiving data from. It must be on that agency's/department's letterhead and should include both

1) *that the release of the desired data is legal and*

2) *that the entity is willing to release the desired data to you, the researcher. If you are not receiving data, this letter should indicate that you are supported.*

***For VSAC requests, if you do not have a Departmental Letter of Support (LOS)/Data Release, you may upload a copy of the Data Request Form (application) from the department to secure a review for the upcoming cycle. The protocol will not be approved until the LOS is uploaded to the protocol.*

Please also review the CPHS Statement for Birth and Death Data.

VSAC Data Request Application – Placeholder.pdf Department Letter of Support

Deleted Attachments: 13 (Most Recent: VSAC Data Request Application – Placeholder.pdf on 01/04/2026 10:31 PM ET)

PREVENTING RE-USE AND UNAUTHORIZED ACCESS

Explain how you will ensure that data will not be reused or provided to any unauthorized person or entity.

Unauthorized means that the person or entity does not have a need to access the data for purposes of the research project approved by CPHS.

Unauthorized means that the person or entity does not have a need to access the data for purposes of the research project approved by CPHS.

Data will be kept in a secure physical storage place (in a locked room) and the only electronic copy will live in an encrypted USB drive with only authorized persons who have access. The USB drive will be securely wiped and destroyed once this project is complete. Only one computer will be equipped with the software to read the USB drive that has been encrypted with Veracrypt (this software is FIPS 140-2 compliant).

CONFIDENTIALITY OF PUBLISHED DATA

Indicate whether information will be published that could possibly be used to identify an individual subject.

Information that could possibly identify an individual subject will NOT be published.

DATA REQUEST JUSTIFICATION

Provide adequate justifications for the quantity of the data, the years and the variables being requested. Have you requested no more than the minimum necessary data to perform the research?

All justifications for variables are included in the previously attached CDPH excel sheets. We are requesting dynamic data until 2029 so that we may continue to send recruitment letters to new parents for the years to come, and thus be able to continue fulfilling the previously described benefits for years to come.

LIMITATIONS TO DATA ACCESS

Indicate if access to data is limited only to those with a need to know for purposes of implementing or evaluating the research.

Yes, access to data is limited only to those with a need to know for the purpose of completing the mailings of recruitment letters as we receive the data through 2029.

PROTECTION AGAINST SMALL CELL SIZES AND ASSOCIATED PROBLEMS

Describe appropriate and sufficient methods to protect the identity of individual subjects when small cells or small numbers and/or data linkage to another data set are involved in the research project.

To comply with California Health & Human Services Agency (CalHHS) Data Deidentification Guidelines (DDG), researchers must ensure that no cell size smaller than 11 is reported to prevent potential re-identification of individuals. Please describe your de-identification methodology, including:
• How small cell sizes are suppressed and whether the CalHHS DDG standard (minimum cell size of 11) is being followed.
• Any additional suppression techniques used beyond the standard guidelines.
• How your team will address situations where small cells may arise unexpectedly (e.g., when reporting on small sites, unique roles, or rare characteristics).
Providing a detailed explanation will help reviewers verify compliance with privacy and data protection standards.

01/02/2026 • Sussan Atifeh • *Not* Internal

Please indicate that data will be redacted to meet DDG guidelines.

01/20/2026 • Jonni Johnson, PhD • Internal

The UCI IRB is already attuned to this and no research studies that use the database will use a cell size that precludes anonymity. For recruitment purposes we will always send mailers to at least 1,000 addresses to ensure cell size requirements are met.

LINKAGES

Will the data set be linked with any other data sets?

are you not linking the birth and death data together? That process is not described anywhere.

01/20/2026 • Jonni Johnson, PhD • Internal

No

DESTRUCTION OF PID VERIFICATION

Indicate that you will provide CPHS with a letter certifying that PID has been destroyed and/or returned to the data source once research is concluded.

Yes

DATA SECURITY LETTER

Please obtain a Data Security Letter (DSL) from UCI using the format specified on the CPHS website. The link in the attached document does not open the relevant page.

For your convenience, you can access the relevant resources using the links below:

• Data Security Letter Template
https://www.cdii.ca.gov/wp-content/uploads/2024/03/Data-Security-Letter-Template-Accessible.pdf

• Data Security Requirements
https://www.cdii.ca.gov/wp-content/uploads/2023/04/Data-Security-Requirements-2012-04-20.pdf

01/02/2026 • Sussan Atifeh • *Not* Internal • Resolved

Upload a certification/statement from the Chief Information Officer, Privacy Officer, Security Officer or equivalent position of the researcher's institution that CPHS Data Security Standards are met.

- *Data security letters cannot be signed by the Principal Investigator or Responsible Official.*
- *The data security letter must be on your institution's letterhead.*
- *Example of data security letter*

Data Security Requirement Letter_signed_updated link.pdf Data Security Letter

Deleted Attachments: 2 (Most Recent: Data Security Requirement Letter_signed_updated link.pdf on 01/04/2026 10:31 PM ET)

Physical Safeguards

DATA PROTECTION

Indicate that research records and physical samples will be protected through the use of locked cabinets and locked rooms; PID in paper form will not be left unattended unless locked in a file cabinet, file room, desk, or office.

Yes

DATA DESTRUCTION

Will data/samples will be destroyed or returned as soon as it is no longer needed for the research project.

Yes

RETAINED DATA

Will the retained data/samples have personal identifiers or be de-identified?

data will contain personal identifiers

DESTRUCTION METHODS

Describe how you will ensure the PID in paper form is disposed of through confidential means, such as cross cut shredding or pulverizing.

There will be no PID in paper form.

FAXING

Describe how you will ensure that faxes with PID are not left unattended and fax machines are in secure areas.

There will be no faxes with PID.

MAILING

Indicate whether mailings of PID are sealed and secured from inappropriate viewing; and whether mailings of 500 or more individually identifiable records of PID in a single package, and all mailings of PID to vendors/contractors/co-researchers, are sent using a tracked mailing method, which includes verification of delivery and receipt, such as UPS, U.S. Express Mail, or Federal Express, or by bonded courier.

The recruitment letters mailed will not contain access to any PID. The mailers will only be addressed to a parent (name and mailing address), but no other data will be included.

ELECTRONIC STORAGE

State whether PID in paper or electronic form, e.g., stored on laptop computers and portable electronic storage media (e.g., USB drives and CDs), will ever be left unattended in cars or other unsecured locations.

why is a portable device being used with this data? Can server space be dedicated to this? It seems unnecessarily risky to keep data on a portable device unless the USB never leaves the locked room?

01/20/2026 • Jonni Johnson, PhD • Internal

PID will be stored on a USB drive and will not be left unattended in unsecured locations.

PHYSICAL STORAGE

Describe whether facilities, which store PID in paper or electronic form, have controlled access procedures, and 24 hour guard or monitored alarm service.

Facilities will have controlled access procedures, a locked a room and locked storage.

SERVER SECURITY

Provide a description of whether all servers containing unencrypted PID are housed in a secure room with controlled access procedures.

Not applicable. PID will be stored on an encrypted USB drive.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

Yes, they will be stored separately.

DISK STORAGE

State whether all disks with PID will be destroyed.

Yes, the encrypted USB drive will be destroyed.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

State whether all computer access will be protected through the use of encryption, passwords, and other protections.

Yes, all computer access will be protected through the use of encryption, passwords, and other protections.

FIPS 140-2 COMPLIANCE: WORKSTATIONS

Indicate whether all workstations that contain PID have full disc encryption that uses FIPS 140-2 compliant software. If not, explain why not and what encryption will be used.

Not applicable. The only location for the data will be the encrypted USB drive.

FIPS 140-2 COMPLIANCE: LAPTOPS

Indicate if all laptops that contain PID have full disc encryption that uses FIPS 140-2 compliant software. If not, explain why not and what encryption will be used.

Not applicable. The only location for the data will be the encrypted USB drive.

FIPS 140-2 COMPLIANCE: REMOVABLE MEDIA DEVICES

Indicate if PID on removable media devices (e.g. USB thumb drives, CD/DVD, smartphones, backup recordings) are encrypted with software that is FIPS 140-2 compliant.

Yes, PID stored on the USB drive will be encrypted with Veracrypt. This software is FIPS 140-2 compliant.

SECURITY PATCHES

Indicate if all workstations, laptops and other systems that process and/or store PID have security patches applied in a reasonable time frame.

Yes, security patches are applied as they are approved by the institution in a reasonable time frame.

PASSWORD CONTROLS

Indicate if sufficiently strong password controls are in place to protect PID stored on workstations, laptops, servers, and removable media.

Yes, the encrypted drive storing the media will have a strong passcode and will be FIPS 140-2 compliant. As previously stated, the only place that PID will be stored is on a USB drive.

ELECTRONIC SECURITY CONTROLS

Indicate if sufficient system security controls are in place for automatic screen timeout, automated audit trails, intrusion detection, anti-virus, and periodic system security/log reviews.

Automatic screen timeout, intrusion detection, and anti-virus security will be in place.

FIPS 140-2 COMPLIANCE: ELECTRONIC TRANSMISSION

Explain whether all transmissions of electronic PID outside the secure internal network (e.g., emails, website access, and file transfer) are encrypted using software which is compliant with FIPS 140-2.

Not applicable. There will be no electronic transmission once we receive the data.

INTERNET ACCESSIBILITY

Note if PID in an electronic form will be accessible to the internet.

PID in electronic form will NOT be accessible to the internet.

DISPOSING OF PID

When disposing of electronic PID, indicate whether sufficiently secure wiping, degaussing, or physical destruction will be used.

CPHS needs a brief description of how electronic PID from state records will be securely destroyed, including the specific method (e.g., secure wiping/overwriting, degaussing, or physical destruction), who performs the destruction, and when it will occur. Please update this section with enough detail to demonstrate that the disposal process meets secure standards.

01/02/2026 • Sussan Atifeh • *Not* Internal • Resolved

When disposing of electronic PID, we will wipe and physically destroy it securely. First, the Principal Investigator will ensure that electronic data are permanently deleted using institutionally approved secure wiping/overwriting methods that render the data unrecoverable. Then, the authorized institutional IT personnel will destroy and decommissioned any electronic media that stored PID and follow established information security procedures.

Conflict of Interest Information

CONFLICT OF INTEREST (COI) INSTRUCTIONS

A COI is defined as any financial or other relationships of the researcher(s) or the institution that could be perceived as affecting the objective conduct of the research, including the interpretation and publication of the findings. Researchers must disclose any COI, including perceived COI.

Financial relationships to be disclosed include but are not limited to the following:

- **Present or anticipated ownership of stock, stock options, or other financial obligations of the source of funding.**
- **Receipt or expectation of payment of any sort in connection with papers, symposia, consulting, editing, etc. from the source of funding.**
- **The sale or licensing or anticipated sale or licensing of medical or other products or intellectual property, such as patents, copyrights, or trade secrets to the source of funding or other entities.**
- **Any past, present or anticipated receipt of money or other valuable consideration from the source of research funding by the researcher(s), the family of the researcher(s), the research institution, or by an institution in which the researcher(s) or the family of the researcher(s) has an interest as owner, creditor, or officer.**

DISCLOSURES

Does any member of the study team, members' spouses, or members' dependent children have any significant financial interests related to the work to be conducted as part of the above-referenced project?

No

Informed Consent Procedures

INFORMED CONSENT PROCEDURES

Provide a description of procedures to be used in obtaining and documenting informed consent from participants.

See instructions and examples on CPHS website.

We will not have contact with interested individuals as they are accessing our recruitment letter. If parents are interested in participating, they will voluntarily provide information in order to sign up for the study. The informed consent process will take place in the lab at UC Irvine prior to participating. Parents and children will be informed about the study, and given as much time as they would like to review the consent form before signing and completing study activities. Consent forms will vary depending on the age of the child

CONSENT FORMS

Attach copies of consent forms and any other documents or oral scripts used to inform potential research subjects about the study. See examples of consent and assent forms on the CPHS website.

Be sure to include a concise explanation of key information for participants at the beginning of your consent form, as shown in the examples on the website. Also attach the Participant's Bill of Rights (download the revised version from the same CPHS website). CPHS may approve the use of a consent procedure which does not include, or which alters, some or all of the elements of informed consent. If a waiver or alteration of informed consent is being requested, attach a document that explains how all of the criteria below will be satisfied.

20118468 Consent Form (0-5) 08-05-22.pdf	Consent Form
20195464 Parent Consent (5-7) 6-18-25.pdf	Consent Form
20195464 Parent Consent Form (3-5) 4-24-2025.pdf	Consent Form
20195464 Parent Consent Form (8-13) 4-24-2025.pdf	Consent Form

TRANSLATED DOCUMENTS

Provide copies of the non-English version of consent/assent forms and/or scripts to be used in this research.

20195464 Spanish Parent Consent (5-7) 6-18-25.pdf Consent Form

Deleted Attachments: 1 (Most Recent: 20195464 Spanish Parent Consent (5-7) 6-18-25 (2).pdf on 01/07/2026 4:13 PM ET)

TRANSLATOR

Provide a copy of the curriculum vitae of the translators(s) and/or proof of certification of the translation firm.

CPHS may reject poorly written documents or documents from translators lacking adequate proof of training or expertise. For studies using documents translated into Spanish, the translation should use formal language.

KarlaGalvan_APscore_Spanish.pdf Translator Curriculum Vitae

Deleted Attachments: 1 (Most Recent: KarlaGalvan_APscore_Spanish (1).pdf on 01/07/2026 4:13 PM ET)

Informed Consent Waiver

INFORMED CONSENT WAIVER

Are you requesting a waiver or alteration of informed consent?

No

HIPAA Determination

HIPAA INSTRUCTIONS

To determine if this project is covered by HIPAA, answer the following questions.

COVERED ENTITY

Will health information be obtained from a covered entity, known as a clearinghouse, such as Blue Cross, that processes or facilitates processing health data from another entity, including but not limited to state databases?

No

HEALTHCARE PROVISIONS

Will the study involve the provision of healthcare by a covered entity, such as the UCD Medical Center?

No

OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

No

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

> You mentioned, this project is University funded. Please change your response in this section to "Yes" and attach a copy of the project's budget in this section.
> 01/02/2026 • Sussan Atifeh • *Not* Internal • Resolved

Yes

Attach a copy of your project budget here

Child Development Study Budget.docx.pdf Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

Cover Letter Richland 8.19.25.pdf Cover Letter

Deleted Attachments: 1 (Most Recent: Cover Letter Richland 8.19.25.pdf on 01/04/2026 10:31 PM ET)

In order for the PI to review and sign this form, you will need to click "Next" and on the next page, click "Submit." At that point the PI will receive notification that will need to review the application and if they request changes, they will return the form to you and you will receive an email notification.

Calculated Field for agency plus data set *(Internal)*

California Department of Public Health: Vital Statistics

PI Signature for Coordinator Submission (Initial)
- Submitted 01/08/2026 5:21 PM ET by Lindsey Richland, PhD

PI Review

Please click "Next" and "Submit" in order to submit this application, regardless of whether or not it is ready for review. If you indicated it is ready for review, it will go to the Responsible Official for review and signature, and if not, it will be returned to the individual who completed the form for changes.

Is this application ready to be reviewed by the IRB? If not, choose no to have the application sent back to the coordinator for revisions.

Yes

To sign this form, enter your IRBManager password. By signing this form, you are indicating that the information within this application is accurate and reflects the proposed research and that you attest to the conflict of interest disclosures for all study team members.

Signed Thursday, January 8, 2026 5:21:09 PM ET by Lindsey Richland, PhD

Responsible Official Signature
- Submitted 01/08/2026 6:01 PM ET by Julie Washington, PhD

Responsible Official Signature

After reviewing this application, is it ready for submission to the CPHS IRB?

Yes, ready for submission to IRB.

Enter your password to sign this protocol. By signing this protocol, you are attesting that the information within is accurate and reflects the details of the proposed research project.

Signed Thursday, January 8, 2026 6:01:02 PM ET by Julie Washington, PhD

After choosing whether or not the submission is ready for CPHS IRB review, please click "next" and "submit" (on the next screen) to move the form forward to the CPHS IRB or back to the Researcher.

Notify IRB for Pre-Screening
- Submitted 01/09/2026 2:19 PM ET by Sussan Atifeh

Internal IRB Screening

CPHS Office: The questions on this page will appear every time the project is resubmitted to the CPHS IRB (even after review). Once the project has been reviewed by a committee member, unless researcher has changed questions on the form that impact the level of review, you do not need to update the questions here. If the changes made are not clear and require additional clarification change the 'ready for review' to 'no' and require changes. When you change the answer back to yes, it will remember your previous answers.

Is this study ready to be reviewed by the CPHS panel?

Yes

Choose the IRB committee to review this study (this defaults to CPHS)

CPHS

Level of Review Determination (once the level of review is assigned for this project, do not change this answer unless the reviewer/committee has decided that the study requires a different level of review)

Full Board Minimal Risk

Please provide a rationale for your level of review preliminary determination
This is a study with Human Subjects' Contacts components. Researchers plan to request California birth and death records solely to obtain parent names and mailing addresses so they can send recruitment letters inviting families to participate.

Choose the CPHS Chair
Larry Dickey, MD, MPH, MSW

Select the vice chair of the committee
Larry Dickey, MD, MPH, MSW

Assign to Cycle

February

Assign to cycle year
2026

Load into IRBManager (Initial Submission)
- Submitted 01/09/2026 2:20 PM ET by The System

Chair Review and Full Board Set-Up
- Submitted 01/20/2026 11:58 AM ET by Sussan Atifeh

Full Board Set Up

Project number

2026-004

The office will complete the questions on this page and submit the form after the teleconference with the chairs regarding this project is completed.

Confirmation of level of review

Full Board Minimal Risk

Provide the rationale for the level of review determination
This project has human subjects' contacts components and should be discussed in the CPHS February 6th, 2026, Full Board meeting

Assign SME to study

Jonni Johnson, PhD

Enter the meeting date for this project

02/06/2026

SME Review

SME review

After reviewing the application, complete the question(s) below. If you wish to make comments on the application for the researcher, use the 'add note' feature on each question (be certain to unmark the internal only box and do not mark changes required). To navigate the application, you can either use the 'previous' button at the bottom of the page or from the drop down at the top of this page choose 'view previous stages'. Once you have completed the questions that appear on this page (different questions will appear depending on your answer to the first question), you will need to click 'next' (from either the top of the bottom of the screen) and then click 'submit'.

If you are requiring revisions before the full committee review, the form will be returned to the researcher for revisions and returned to you upon re-submission.

Does the researcher need to provide additional information/revisions before the committee meeting? If there is insufficient time for the researcher to make changes prior to the committee meeting, choose 'no' in order to route the form correctly.

No answer provided.

In order to either return this application to the researcher or to move forward for the full meeting review, click 'next' and 'submit' on the next screen.