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 09/05/2025 5:24 PM ET by Jonathan Hoonhout, CRA

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

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.

Emily Putnam-Hornstein, PhD

Email: eph@unc.edu **Business:** (917) 282-7861

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

University of North Carolina, Chapel Hill

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

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

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

North Carolina

Attach a copy of the PI's Curriculum Vitae.

Putnam-Hornstein-CV_June-2025_Emily-Putnam-Hornste.pdf	PI Curriculum Vitae

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.

Rebecca Rebbe, PhD
Email: rebbe@unc.edu **Business:** (971) 409-8631

Regan Foust, PhD
Email: rfoust@usc.edu **Business:** (714) 272-9105

John Prindle, PhD
Email: jprindle@usc.edu **Business:** (805) 559-1312

Attach a copy of each Co-PI's Curriculum Vitae.

cv_rebbe_070825.pdf	Co-PI Curriculum Vitae
Foust, CV 5.21.2025.pdf	Co-PI Curriculum Vitae
jprindle-cv.pdf	Co-PI Curriculum Vitae

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.

Jonathan Hoonhout, CRA
Email: hoonhout@usc.edu **Business:** (213) 821-3587

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.*

Sheryl Zimmerman, PhD
Email: Sheryl_Zimmerman@unc.edu **Business:** (919) 962-6417

OTHER RESEARCH STAFF

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

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.

Jacquelyn McCroskey, DSW

Email: mccroske@usc.edu **Business:** (213) 740-2004

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

False

Project Information

SUBMITTER

Application completed by:

Jonathan Hoonhout, CRA

Email: hoonhout@usc.edu **Business:** (213) 821-3587

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).

Supporting a Strong Start for California Kids

PROJECT SITE

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

University of North Carolina

STUDY PROCEDURES

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

Data Registry
Recruitment-Participant
Surveys

TYPE OF RESEARCH REQUEST

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

*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.

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

Consent form

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.

Economically or Educationally Disadvantaged Persons

FUNDING

Is this research funded?

Yes

Indicate the funding source for this project.
State funded

Enter name of state-funded source.
First 5 California

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.

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.

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

10/03/2025

ANTICIPATED PROJECT END DATE

06/30/2028

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.

This study seeks to gather information from families of newborns in California that would help us better understand eligible non-participation from the family's perspective, including: (1) perceptions of community-based voluntary supports and services, specifically those that operate adjacent to, or supplemental programming program through, the public benefit system; (2) factors influencing uptake of available services (e.g., barriers and facilitators); and (3) self-reported service / support needs, and whether there are variations by sociodemographic, household, or other characteristics.

We are seeking permission to receive monthly and use information on vital birth records scored according to the Strong Start (www.strongstartindex.org) scoring schema to develop a representative sample of children born in each county, with an oversampling of children who are born into families with the fewest assets. We plan to receive 6 months of birth records and engage in active solicitation and enrollment over the 6 month period, as well as 6 months afterward for a total of 12 months. Families meeting eligibility criteria would be contacted with the goal of enrolling, consenting, and completing a short survey about their household composition and resources, service experiences, barriers, and needs either online or over the phone, for which they will receive remuneration in the form of a gift card. The initial engagement should take no more than 20 minutes inclusive of initial consent and study registration.

The data developed through this direct data collection effort would not only better characterize the service landscape at both a local and state level, but also the needs, experiences, and challenges new parents may face in accessing those supports. And, with its focus on families at highest risk of adverse outcomes, it would also help us align needs and supports, evaluate and improve programs, and refine engagement strategies. Finally, it is important to give voice to the experiences of the families of young children and for public agencies to hear directly from families for whom these services were designed. Overall, this work aims to fill a major gap in our understanding of our most vulnerable Californians and promote a strong start for all children statewide.

MAJOR RESEARCH QUESTION

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

This study seeks to gather information from families of newborns in California that would help us better understand eligible non-participation from the family's perspective, including: (1) perceptions of community-based voluntary supports and services, specifically those that operate adjacent to, or supplemental programming program through, the public benefit system; (2) factors influencing uptake of available services (e.g., barriers and facilitators); and (3) self-reported service / support needs, and whether there are variations by sociodemographic, household, or other characteristics.

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

Study procedures are noted below:
The Research Team (i.e., the PI, Co-PIs, and other UNC and USC Research Staff) would receive and link monthly extracts of vital birth and death records from VSAC in a highly secure computing environment (Details described in Administrative Safeguard section). The lead data scientist leading the linkage has extensive experience linking administrative records and has securely worked with vital records for over a decade. The Research Team would construct the research sample:
At the outset, records indicating maternal or neonatal death (as identified through linkage with vital death records) and births to mothers under age 18 years of age at the time of birth (as identified through DOB listed on the birth record) will be excluded from the sample.
Remaining records will be scored according to the Strong Start Index schema, with the aim of developing a representative sample of families within CA counties and across the Strong Start Asset Spectrum, with an oversampling of families with the fewest assets.
Each of the records in the resulting research sample will be provided an encrypted Study ID allowing for data to be re-integrated with information from vital birth records.
The Research Team would then create two files:
An analytic file that has been stripped of personal identifiers, but retains encrypted Study IDs to facilitate integration with survey responses; and
A file with only the information necessary to contact the research sample (and, importantly, NOT the encrypted Study ID) that would be securely transferred (via SFTP or other secure file-sharing mechanism) to the Survey Administrator.
Next, the Survey Administrator (i.e., Verasight) would initiate and implement solicitation, consenting, participation, and renumeration procedures.
Using identifying information from the vital records, the Survey Administrator will use all applicable information that can be obtained directly from the record. In an effort to obtain additional contact information for each parent named in the birth record in the research sample, the Survey Administrator will use trusted voter and consumer record databases, which employ proprietary algorithms and use information such as birth date, full name, and street address.
The Survey Administrator will then contact participants using multi-lingual and multi-modal methods to enroll, consent, and facilitate completion of a short survey module (described in more detail in the Recruitment Section below). The survey module will be digital, accessed through a protected page on a website and administered using Qualtrix. There will also be an option for phone administration if a participant prefers. Study material will be available in English, Spanish, and potentially Chinese, Tagalog, Korean, and Vietnamese, the six most common languages spoken in California.

NOTE: Only English versions are provided at this time. In the interest of efficiency, we are waiting to translate the study materials into Spanish and potential other languages until the Committee has the chance to review and endorse the completed protocol. We will submit translated copies upon finalization.
The initial engagement should take no more than 20 minutes inclusive of initial consent and study registration.
Participants would receive remuneration for module completion in the form of an immediately accessible digital gift card.
The Research Team and Survey Administrator would examine the distribution of responses and response rates, in order to refine solicitation and remuneration strategies for future cohorts.
In addition, the Research Team would analyze and disseminate the results. This would include producing aggregated (de-identified) research results and associated materials, as well as analyzing the most recent birth files to characterize the population of babies being born, model demographic trends, and develop population projections.
Survey Module is attached. Please note that at this stage, we are only requesting CPHS review and approval for the contents of the first survey module. We hope that, should response rates and funding permit, we would be able to seek approval for additional survey modules. As such, our consent protocols will include reference to more than one module.

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.

Survey_Putnam Hornstein.pdf Other Documents

Deleted Attachments: 3 (Most Recent: Survey_Putnam Hornstein.pdf on 09/05/2025 4:13 PM ET)

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 Birth Records
California Department of Public Health	Vital Death Records

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.

Our sample will be constructed from the full population of children born in CA born over a 6 month period, with an oversampling of children whose characteristics at birth have been shown to be associated with heightened rates of childhood adversities (i.e., children with relatively few Strong Start assets), along with geographic considerations to ensure representativeness across CA counties.

Based on historical estimates, about 33,000 babies are born per month. About half (49%, n=16,000) were Hispanic/Latino, 27% (n=9,000) were White, 14% (n=4,500) were Asian/Pacific Islander, 5% (n=1,600) were Black, and 5% (n=1,600) were of another race/ethnicity.

Assuming active recruitment for individuals in 6 months of birth records, our Total estimated study sample would be about 200,000, with the following racial/ethnic breakdown: about 100,000 Hispanic/Latino parents, 54,000 White parents, 27,000 Asian/Pacific Islander parents, 10,000 Black parents, and 10,000 parents of another race/ethnicity.
We are planning to oversample mothers most likely to be eligible for the voluntary community-based programs on which the modules will be focused. Oversampling the 20% of families with the fewest Strong Start assets would produce a Targeted study sample would be about 40,000, with the following racial/ethnic breakdown: about 20,000 Hispanic/Latino parents, 1,700 White parents, 600 Asian/Pacific Islander parents, 5,000 Black parents, and 2,600 parents of another race/ethnicity.

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.

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.

Please see attachment "Putnamhornstein_Variable List_CPHS_07282025" for a list of all variables and databases. A justification for each variable has also been provided.

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.

Putnamhornstein_Variable List_CPHS_07282025.xlsx List of Variables

RATIONALE

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

The public, private, philanthropic, and non-profit sectors have invested significant resources in developing, marketing, administering, and evaluating supportive services for vulnerable children and families. Home visiting programs, subsidized child care, family support centers, other community-based voluntary services, and programs that operate adjacent or ancillary to the public benefit system (e.g., CalWORKs Home Visitation) have proven successful in supporting families during times of crisis and mitigating immediate and long-term deleterious outcomes.

Eligible non-participation in these programs, however, is common.1–10 Even more concerning, many of the most intensive interventions designed to reach the most vulnerable families have low uptake and engagement.1–3

In order to really move the needle in terms of mitigating risk and improving outcomes for children, we need to better understand the reasons behind eligible non-participation, especially among children with the highest rates of adverse outcomes. Several ongoing surveys speak to the barriers, benefits, and challenges parents of young children may face in accessing the current array of supports they need at a local level,11–14 but none help us understand the needs and experiences of families who don't engage, but are at high risk of poor outcomes.

Developing the research sample based on the entire birth cohort would allow for the examination of service experiences, barriers, and needs not only of families who engaged in services, but also those who did not. Oversampling children whose characteristics at birth have been shown to be associated with heightened rates of childhood adversities, along with geographic considerations, would help to ensure that we are receiving information from families across the Strong Start spectrum and that we are achieving representativeness across CA counties.

1. Prindle J, Ahn E, Foust R, Putnam-Hornstein E. Identifying risk of child welfare involvement in Orange County births with the Bridges Program. Child Youth Serv Rev. 2024;156:107383. doi:10.1016/j.childyouth.2023.107383
2. Foust R, Prindle J, Eastman AL, et al. Antelope Valley Partners for Health Home Visiting Linkage Memo.; 2019.
3. Radcliff E, Breneman CB, Crouch E, Baldwin I. Are We Serving the Most At-Risk Communities? Examining the Reach of a South Carolina Home Visiting Program. J Community Health. 2019;44(4):764-771.
4. Breidenbach AL, Heinz H, Acharya B, Jimenez EY. Why Don't Families Apply for Child Care Subsidies? Results from a Survey of Subsidy Users and Non-Users in New Mexico. Social Science Research Network. Preprint posted online April 13, 2025. doi:10.2139/ssrn.5211199
5. Paige D, Caulfield L, Gross S. White Paper: Evaluation of Innovative Strategies to Increase Child Participation and Retention in the Special

Supplemental Nutrition Program for Women, Infants, and Children (WIC).
6. National- and State-Level Estimates of WIC Eligibility and Program Reach in 2022 | Food and Nutrition Service. Accessed July 24, 2025. https://www.fns.usda.gov/research/wic/eer-2022
7. Schanzenbach DW. Understanding SNAP: An overview of recent research. Food Policy. 2023;114:102397. doi:10.1016/j.foodpol.2022.102397
8. BARNES C. "I Can't Get Ahold of Them": Perceptions of Administrative Burden and Administrative Exclusion across SNAP, WIC, and Medicaid during the COVID-19 Pandemic. Ann Am Acad Pol Soc Sci. 2023;706(1):118-136. doi:10.1177/00027162231201759
9. Sheridan M, Ferrant C. Participation in the Women, Infants and Children (WIC) Program: A Synthesis of the Literature.
10. Maneely J, Neuberger Z. Using Data Matching and Targeted Outreach to Enroll Families With Young Children in WIC.
11. Maternal and Infant Health Assessment. Accessed February 5, 2023. https://www.cdph.ca.gov/Programs/CFH/DMCAH/MIHA/Pages/default.aspx
12. RAPID Survey. Accessed July 23, 2025. https://rapidsurveyproject.com/
13. California Health Interview Survey (CHIS). Accessed July 23, 2025. https://healthpolicy.ucla.edu/our-work/california-health-interview-survey-chis
14. About the National Survey of Children's Health. Accessed July 23, 2025. https://www.childhealthdata.org/learn-about-the-nsch/NSCH

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.)?

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

Recruitment method: Outreach to the eligible sample.

Respondents in the study sample will be contacted via mail (letters, post cards) at the address listed on the birth record. Parents will receive at least 1 invitation and 1 reminder via mail. The mailed survey invitations will include options to respond by scanning a QR code, calling a phone number, or typing in a web address.

We are seeking to receive birth records on a monthly cadence. Verasight will explore experiments to increase response rates, which might include sending additional mail reminders or offering an option for respondents to mail back their responses instead of taking the survey online or by telephone.

Where email is available, we may email survey invitations. Where phone numbers are available, we may also text or call eligible at-risk parents to invite them to participate in the study. For live calls, our research team will extensively train the phone agents to explain the purpose of the study, options for participation, and how parents will receive the incentive. In the event that parents do not answer the phone call, agents will leave a voicemail and provide a call back number. If eligible participants answer the phone call and agree to participate, agents will be able to interview respondents directly and/or transfer them to a pre-recorded automated survey system.

Attach copies of all recruitment materials.

[EXTERNAL] Letter draft.pdf	Recruitment Materials
PostcardCaliforniaparents-option1.pdf	Recruitment Materials

Deleted Attachments: 1 (Most Recent: Foust, CV 5.21.2025.pdf on 09/05/2025 3:59 PM ET)

SCREENING

Will subjects be screened prior to entry into the research?

Not Applicable

COMPENSATION

Will subjects be compensated for participating in the study?

Yes

Compensation type
Gift card

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.
Those who qualify and complete the survey will be compensated with an electronic gift card that can be cashed out to a variety of stores such as Walmart, Starbucks, or Amazon. Study compensation will be sent to the email address provided by the respondent. Compensation is sent immediately after survey completion and usually arrives within 5 minutes of survey submission.

Amount: Some respondents may be offered a small preincentive (ex: $1) to increase their trust in the survey firm. Verasight will experiment with the best methods to increase response rates, which may include experimentation with incentive amounts or delivery schedule. with incentive amounts or delivery schedule. Respondents will be compensated between $20 and $30 for module completion. We will monitor response rates in the first 45 days and adjust the remuneration amount as needed.

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.

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.

The study, itself, has an anticipated conclusion date of June 30th, 2028. We plan to receive 6 months of birth records and engage in active solicitation and enrollment over the 6 month period, as well as 6 months afterward for a total of 12 months. Families in the research sample will be asked to respond to one survey module shortly after birth. The survey will consist of short multiple choice questions. There will be no open-ended questions on the survey. The multi-modal module will take no more than 10 minutes, amounting to a total commitment of no more than 20 minutes, inclusive of initial consent and study registration.

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.

This is a minimal risk project.
First, robust procedures will be in place to ensure that the research sample only includes adults 18 years or older and does not include individuals whose infant has passed away. Second, the survey questions will focus on perceptions of community-based voluntary service experiences, barriers, and needs, as well as household characteristics and resources. One question confirms a recent birth and that child is still living with the respondent and one question asks about social determinants of health (e.g., ACEs), but no other sensitive questions are asked on the survey. Third, there will be no direct identifiers on the survey, only an encrypted linkage key that will be used to link a participant's birth record to their survey response. The direct identifiers on the birth record will be kept separate from both the analytic information on the birth record and the survey responses in order to adhere to the separation principle and further protect participant confidentiality.

Two potential risks have been identified:
1. Psychological distress as a result of contact following the loss of a child. The Research Team is guarding against that risk through ongoing linkages to vital records.
2. Loss of confidentiality due to a data breach. However, all best practices will be followed to ensure data security including: use of encrypted identifiers, secure data environments, and an experienced survey firm, Verasight. Verasight has been successful in engaging a number of hard-to-reach populations, including youth aging out of the foster care system, policy-makers, and families who had lapsed participation in a longitudinal study for over a decade, for example.

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.

No services will be provided given the nature of the standard nature of the questions and the recruitment procedures.

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.

As described above, this is a minimal risk project.

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 will be no direct benefits to any individual participants, however, the knowledge gained through this effort would not only better characterize the service landscape at both a local and state level, but also the needs, experiences, and challenges new parents may face in accessing those supports. And, with its focus on families at highest risk of adverse outcomes, it would also help us align needs and supports, evaluate and improve programs, and refine engagement strategies. Finally, it is important to give voice to the experiences of the families of young children and for public agencies to hear directly from families for whom these services were designed. Overall, this work aims to fill a major gap in our understanding of our most vulnerable Californians and promote a strong start for all children statewide.

JUSTIFICATION OF RISKS

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

This low-risk project involving a short (20-minute remunerated survey, inclusive of consenting procedures) aims to enhance our understanding of the service landscape at both local and state levels, focusing on the service needs, experiences, and challenges faced by new parents in accessing supports. By concentrating on families with the highest rates of adverse outcomes and, thus, who are most likely to be eligible for community-based voluntary programming, it will help us better align services with those needs, assess and improve existing programs, and refine engagement strategies. Additionally, it is crucial to amplify the voices of families with young children, ensuring that public agencies hear directly from the individuals these services are intended to support.

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)
Telephone numbers
Email address

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.

Members of the Research Team who would have access to PID are longstanding members of the Children's Data Network team and have safely / securely worked with vital records and other sensitive administrative data going back a decade.

Employees of the Survey Administrator, Verasight, undergo routine training on data security. They also have stringent Access Management Controls: Role-based access control (RBAC), multi-factor authentication (MFA), and least-privilege principles are enforced across systems.

STAFF VETTING PROCEDURES

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

All staff at the Research Team have undergone rigorous background checks (at either USC or UNC) as part of their hiring process. All Verasight staff administrating the survey have each undergone identity verification and reference checks. Verasight routinely trains employees on privacy and data security procedures. As part of their employment agreement, all employees have signed confidentiality and data security agreements based on stringent standards.

SUPPORT LETTER

Obtain and submit a department support/data release letter.

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.

VSACResearchApplication_Notarized.pdf Department Letter of Support

Deleted Attachments: 1 (Most Recent: Foust, CV 5.21.2025.pdf on 09/05/2025 5:24 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.

Vital Birth and Death records would be securely released (via SFTP or other secure file-sharing mechanism) to the Research Team, the Children's Data Network, within the context of approved protocols and finalized agreements. These records would then be cleaned, normalized, and probabilistically linked in the CDN Data Lab (See below for more information) for the purpose of excluding families who experienced a maternal or neonatal death (as identified through linkage with vital death records) and mothers under age 18 years of age at the time of birth (as identified through DOB listed on the birth record) from the research sample. Remaining records would be scored according to the Strong Start Index schema, with the aim of developing a representative sample of families within CA counties and across the Strong Start asset spectrum, with an oversampling of families with the fewest assets. Each of the records in the resulting research sample would be provided an encrypted Study ID allowing for data to be re-integrated with information from vital birth records.

The Research Team would then create two files: 1) an Analytic file that has been stripped of personal identifiers, but retains encrypted Study IDs to facilitate integration with survey responses; and 2) a file with only the information necessary to contact the research sample (and, importantly, NOT the encrypted Study ID) that would be securely transferred (via SFTP or other secure file-sharing mechanism) to the Survey Administrator.

The Research Team adheres to a strict "separation principle" in our approach to working with data. Personally identifiable data (PID) from records is only processed on designated workstations, by a select group of non-research staff, in highly secure physical environments. PID is used only for record linkage and for solicitation to participate in the study; it is not used or accessed for any analytic purposes. Restricted research (limited) datasets are processed on the CDN's secure data server and accessed through VPN by CDN researchers.
Analytic Files are constructed post-linkage and are restricted research datasets that have been stripped of all direct identifiers (e.g., names, DOBs). These files are transferred to the CDN's secure data server accessible only through VPN access to the institutional domain network. This server has private / designated computing nodes that are not shared with any other projects or research groups. Only approved CDN analysts and affiliated researchers are provided with access to the CDN's secure data server.

Specifically, the CDN's secure data server is accessible only to approved CDN project personnel through credentialed VPN access and a dual authentication process. Affiliated researchers and approved CDN staff must sign confidentiality agreements, be approved by data partners, document that

they have completed general human subjects certification courses and data security trainings, and have ongoing supervision from the PI to ensure adherence to protocols for accessing and processing data in order to gain access to CDN's private, analytic server. Users can only access this secure data server though university Virtual Private Network (VPN), which requires 2-levels of authentication using their university-registered mobile devices and password protection. Furthermore, affiliated users of CDN's private analytic server are limited to their approved directories. With the exception of the PI and Data Scientists, users can only access folders relevant to their designated projects to prevent misuse of data.

Data Lab - SRW
Secure Research Workspace (SRW) will serve as the secure hosting environment for sensitive data containing PID and analytic information. Records will be transferred from agency partners to a designated data custodian with the Children's Data Network / Children's Services Archive via encrypted methods determined by the agency data owner to ensure compliance with state and federal law. Requirements of secure transfer are outlined in each agency MOU or DUA (e.g., records transferred via SFTP).

The SRW environment operates via its FTP system. This system uses a Virtual Private Network (VPN) which features a log system to monitor all actions by all users in addition to automated virus checks of all incoming files into the environment. Importantly, the SRW has two levels of access for any user within its system. At 'Level 1', which is a designation exclusively provided by the Project PI via communication and approval to SRW staff. Designated Level 1 staff are permitted to work with identified records.

Only five members of the Children's Data Network / Children's Services Archive have this level of access, the Project PI (E. Putnam-Hornstein), four long-time members of the CDN (Co-investigators, R. Rebbe & J. Prindle and Senior Data Scientists, H. Nghiem & H. Suthar). These individuals will assume responsibility for the receipt and transfer of data from public agency partners into the SRW. The Data Science team will also assume responsibility for linkage is completed, the analytic files are made which includes the removal of all PID. Since service dates remain, they are essential for analysis, the data is considered 'restricted research data' and is not fully de-identified.

Following record linkage, the restricted research data will then be moved by Level 1 users (see above) to the virtual desktops of the Level 2 researchers for research and analysis. Each Level 2 user will only be able to access the data related to analyses for which the available records are required for them to carry out an approved analysis (coordinated by the Project PI). Notably, and as an additional level of security, Level 2 researchers are not able to directly copy / download (or retrieve) outputs or results analysis carried out on the SRW server. The common 'cut & paste' feature is disabled the workspaces of all users has been set up by SRW as part of their Security System Plan.

In order to receive the outputs of any analysis, Level 2 users must provide a request to a Level 1 user with the output files for retrieval from the SRW

server. The outputs will be reviewed once more to confirm they are free of any PID before leaving the SRW server. All file transmission and retrieval are monitored and tracked by the SRW Platform.

Phil Kaufman, IT Director at UNC-CH School of Social Work, oversees institutional compliance with data security protocols at Data Lab - SRW. The latest security protocols and updates can be found at https://its.unc.edu/research-computing/secure-research-workspace/

The Survey Administrator, Verasight, would receive from the Research Team a file that includes only information necessary for study recruitment. Importantly, the Survey Administrator will not have access to the encrypted Study ID, which would allow for the connection of survey responses with PID. They also employ a number of processes to safeguard respondent data. These include, but are not limited to, practices surrounding data storage, access, and transfer. Specifically, Verasight limits access to survey data to the Verasight project team. Verasight stores all data on secured and encrypted servers only accessible by the Verasight team assigned to the project. We use GoogleDrive to store project materials and data due to their commitment to using industry best practices for security and privacy (https://workspace.google.com/security/?secure-by-design_activeEl=data-centers).
We have selected Qualtrics as our survey programming software because of their rigid security infrastructure (https://www.qualtrics.com/security-statement/). Verasight transfers de-identified data to our clients using secured and encrypted links. Project files can also be password protected at the request of the client.

CONFIDENTIALITY OF PUBLISHED DATA

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

Only aggregated data would be published based on core demographic, geographic, and service experience variables. No personally identifiable information will be published. Academic publications and a report to the funder will adhere to California Health and Human Services Agency (CalHHS) Deidentification Guidelines (DDG) small cell guidelines for aggregation.

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?

We are requesting the minimum information needed: 6 sequential monthly files of birth and death records. The fields requested on the birth and death records are only those required for linkage, targeted enrollment, or analysis.

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.

Access to data is limited to those with a "need to know" for purposes of implementing or evaluating the research. Individualized logins and passwords are provided to personnel with a need to access specific forms of data in support of the project.

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.

Academic publications and a report to the funder will adhere to CHHS DDG small cell guidelines for aggregation. We would also note once again that the nature of the data collected from participants will not be sensitive.

LINKAGES

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

Yes

Identify all data sets and each of the variables to be linked, with a brief description of each variable and justification for each linkage. If there is an extensive list, you may attach that list in the next question and indicate such here.
Yes, as part of this project, the Research Team will link vital birth and death records in the secure Data Lab (details above) using an open source, machine-learning linkage algorithm optimized on records from California. Below, you will find a database listing all data sets and each of the variables to be linked, with a brief description of each variable and justification.

Please note that, while not included in the current application protocol, we do plan to ask participants if they consent to having their data securely linked to other CalHHS administrative datasets so we can passively examine longer-term outcomes of the family. This would, of course, require an amended (or new) protocol submission to CPHS, along with Departmental support and additional funding. We are noting it now, however, as we would appreciate a review of our consent protocol to ensure we have included the appropriate language so as to not preclude this possibility in the future.

Attach a copy of the document detailing all data sets and each of the variables to be linked. If you provided this information in the answer to the above question, skip this question.

Putnamhornstein_Variable List_CPHS_07282025.xlsx Other Documents

Will a third party be used for data linkage?
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

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 Letter_SRW.pdf Data Security Letter

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.

No PID would be maintained in paper form. For more information, please refer to the Administrative Safeguards section above.

FAXING

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

This study will not involve faxes.

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.

PID from CDPH to the Research Team: Would happen via either a secure courier or a secure and encrypted electronic transmission. All data would be encrypted before being transferred. In all cases, encryption keys would be transmitted separately from the data.

PID from the Research Team to the Survey Administrator: Would happen via either a secure courier or a secure and encrypted electronic transmission and would include ONLY the information necessary to solicit study participation and not include the encrypted Study ID. All data are encrypted before being transferred. In all cases, encryption keys are transmitted separately from the data.

PID in mailings to prospective participants: Eligible participants will be contacted at the address provided by state birth records. The letter or post card that we mail will prompt respondents to participate electronically (by scanning a QR code or entering a web address) or by calling a phone number. Respondents will be asked to enter their unique, encrypted Study ID in order to access the survey. No confidential information will be included in information mailed to the family.

For more information, please refer to the Administrative Safeguards section above.

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.

PID in paper or electronic form will never be left unattended in cars or other unsecured locations. PID stored electronically will only contain basic contact information used during the recruitment and solicitation process. For more information, please refer to the Administrative Safeguards section above.

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.

For more information, please refer to the Administrative Safeguards section above.

SERVER SECURITY

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

For more information, please refer to the Administrative Safeguards section above.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

Following separation principles, all PID (with the exception of date and geographic variables) will be stored separately from linked analytic datasets.

Research Team: PID will be stored separately from analytic information(and encrypted Study ID) by the Research Team in their highly secure computing environment.

Survey Administrator: PID used for study recruitment by the Survey Administrator in their secure environment will be stored separately from survey responses. In addition, because the Survey Administrator will not have access to the encrypted Study ID, connecting survey responses to PID outside of the Research Team’s secure Data Lab would be impossible.

For more information, please refer to the Administrative Safeguards section above.

DISK STORAGE

State whether all disks with PID will be destroyed.

All disks with PID will be destroyed at the conclusion of this project and/or in the absence of appropriate CPHS approvals. For more information, please refer to the Administrative Safeguards section above.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

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

All networked computers used to access data are protected through the use of encryption, passwords, and other protections in conformity with University data security protocols. For more information, please refer to the Administrative Safeguards section above.

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.

All workstations that are used to process and analyze data have full disc encryption that uses FIPS 140-2 compliant software. For more information, please refer to the Administrative Safeguards section above.

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.

All laptops containing PID have full disc encryption that uses FIPS 140-2 compliant software. For more information, please refer to the Administrative Safeguards section above.

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.

PID on removable media devices (e.g. USB thumb drives, CD/DVD, smartphones, backup recordings) would be encrypted with software that is FIPS 140-2 compliant. For more information, please refer to the Administrative Safeguards section above.

PID from CDPH to the Research Team: Would happen via either a secure courier or a secure and encrypted electronic transmission. All data would be encrypted before being transferred. In all cases, encryption keys would be transmitted separately from the data.

PID from the Research Team to the Survey Administrator: Would happen via either a secure courier or a secure and encrypted electronic transmission and would include ONLY the information necessary to solicit study participation. All data are encrypted before being transferred. In all cases, encryption keys are transmitted separately from the data.

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.

The Research Team and Survey Administrator will confirm that all systems that process and store PID have up to date security patches.

PASSWORD CONTROLS

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

The Research Team and Survey Administrator will confirm that sufficiently strong password controls are in place to protect PID.

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.

The Research Team and Survey Administrator will confirm that sufficient system security controls are in place for automatic screen timeout, automated audit trails, intrusion detection, anti-virus, and periodic system security/log reviews.

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.

PID from CDPH to the Research Team: Would happen using software that is FIPS 140-2 compliant. All data would be encrypted before being transferred. In all cases, encryption keys would be transmitted separately from the data.

PID from the Research Team to the Survey Administrator: Would happen using software that is FIPS 140-2 compliant and would include ONLY the information necessary to solicit study participation. All data are encrypted before being transferred. In all cases, encryption keys are transmitted separately from the data.

INTERNET ACCESSIBILITY

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

While the Research Team's Data Lab is accessible over an internal network, only encrypted connections are allowed, provided the user has an account, a conforming password, and a conforming client application (SSH / SFTP). All passwords must conform to the maximum strength (length and complexity) setting available. Users are trained in what constitutes a strong password. Usernames are selected which can easily be remembered by the user, but are difficult to guess or look up in lists or dictionaries. No PID used for record linkages are hosted on the secure server with the exception of dates and zip codes needed for analyses.

The PID transmitted to the Survey Administrator for survey recruitment in an electronic form will be transmitted via the secure file sharing service, SendSafely, an end-to-end encrypted platform for the secure exchange of sensitive files and information.

DISPOSING OF PID

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

When the project concludes or we no longer have CPHS and/or agency approval for working with these data, both the Research and Survey Administrator will dispose of all electronic PID through a sufficiently secure wiping, degaussing, or physical destruction. The secure method of data destruction will be documented to CPHS.

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.

Provide a description of procedures to be used in obtaining and documenting informed consent from participants. See instructions and examples on CPHS website.

Respondents in the study sample will be contacted via mail (letters, post cards) at the address listed on the birth record. Parents will receive at least 1 invitation and 1 reminder via mail. The mailed survey invitations will include options to respond by scanning a QR code, calling a phone number, or typing in a web address.

The Survey Administrator will obtain consent electronically (if completing the survey via web) or verbally (if the participant calls in). Please see attached Consent Form. Respondents will opt-in to participate, will be able to stop their participation at any time, and be reminded that identifying information will not be connected to survey responses. The following email address will also be provided should they have questions or concerns: survey.support@verasight.io.

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.

Consent Form_Putnam Hornstein.pdf Consent Form

Deleted Attachments: 3 (Most Recent: Consent Form_Putnam Hornstein.docx.pdf on 09/04/2025 6:19 PM ET)

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?

Yes

Attach a copy of your project budget here

First 5 California int budget_01.06.2025.xlsx Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

Cover Letter_Putnam Hornstein.pdf Cover Letter

Deleted Attachments: 1 (Most Recent: Foust, CV 5.21.2025.pdf on 09/03/2025 7:07 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 Birth Records
California Department of Public Health: Vital Death Records

PI Signature for Coordinator Submission (Initial) - Submitted 09/05/2025 5:28 PM ET by Emily Putnam-Hornstein, 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 Friday, September 5, 2025 5:28:03 PM ET by Emily Putnam-Hornstein, PhD

Responsible Official Signature
- Submitted 09/12/2025 12:55 PM ET by Sheryl Zimmerman, 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 Friday, September 12, 2025 12:55:29 PM ET by Sheryl Zimmerman, 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 09/12/2025 3:39 PM ET by Nicholas Zadrozna

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
Human subject project with data from VSAC

We are seeking permission to receive monthly and use information on vital birth records scored according to the Strong Start (www.strongstartindex.org) scoring schema to develop a representative sample of children born in each county, with an oversampling of children who are born into families with the fewest assets. We plan to receive 6 months of birth records and engage in active solicitation and enrollment over the 6 month period, as well as 6 months afterward for a total of 12 months. Families meeting eligibility criteria would be contacted with the goal of enrolling, consenting, and completing a short survey about their household composition and resources, service experiences, barriers, and needs either online or over the phone, for which they will receive remuneration in the form of a gift card.

Funded: First 5 California

Missing LOS- VSAC application is attached as a placeholder

Choose the CPHS Chair
Catherine Hess, PhD

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

Assign to Cycle

October

Assign to cycle year
2025

Load into IRBManager (Initial Submission)
- Submitted 09/12/2025 3:39 PM ET by The System

Chair Review and Full Board Set-Up

Full Board Set Up

Project number

2025-145

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

No answer provided.

Provide the rationale for the level of review determination
No answer provided.