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 05/12/2025 4:34 PM ET by Christopher Anderson, PhD, MSPH

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

June 2025 cycle.

_____HSC Project_____

_____Non-English Translations_____

• A LOS from CDPH is attached_____minor modification was requested to add "and federal"

• A DSL from Public Health Foundation Enterprise (PHFE) WIC is attached.

05/08/2025 • Sussan Atifeh • Internal

Researchers from Public Health Foundation Enterprise WIC have submitted this application to request approval for a project with Human Subjects' Contacts (HSC).

• PHFE WIC is changing its infant formula policy in 2025 to make lactose-based formula the default and to train staff on formula differences. Researchers will compare babies before and after the change to see if it leads to less use of corn syrup-based formula and healthier growth. Data will be collected from mothers and WIC staff, with findings shared in academic journals and national conferences. The study wants to see how two changes at PHFE WIC affect infant diet and weight gain:
1. Making lactose-based formula the default option for new WIC participants.
2. Training WIC staff about different formula types.

• Data Providing Department: They have requested WIC MIS data on benefit issuance and redemption from CDPH.

•_____ Funding: The research team has applied for funding from the NIH and AHA. The NIH review was delayed and will now happen on May 14, 2025. They expect to get final funding decisions in early June. They assume they

will get funding, but will update CPHS if anything changes.

05/08/2025 • Sussan Atifeh • Internal

Dear researchers: Thank you for addressing all comments. There is only one new comment on page 2 of the application in the "Type of Research Request" section. Please address this comment and resubmit the application. Thank you!

05/12/2025 • Sussan Atifeh • *Not* Internal • Resolved

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.

Christopher Anderson, PhD, MSPH

Email: christophera@phfewic.org **Business:** (626) 430-4212

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

Public Health Foundation Enterprise (PHFE) WIC

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

City of Industry

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.

Christopher Anderson CV 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.

Shannon Whaley, PhD

Email: Shannon@phfewic.org **Business:** (626) 856-6618

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

2025 resume Shannon E. Whaley.doc 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.

Christopher Anderson, PhD, MSPH

Email: christophera@phfewic.org **Business:** (626) 430-4212

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.*

Kiran Saluja, MPH, RD

Email: kiran@phfewic.org **Business:** (626) 856-6650

OTHER RESEARCH STAFF

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

Please ensure you have listed in this section "all" research staff who interact directly with participants (as in interviews or focus groups) or who will have access to the data.
This includes individuals who will have access to the linked de-identified data if that data file will contain any data fields that were originally in the state data.
This includes all research staff who are involved with data management, data processing or analysis and write-up, etc.

05/08/2025 • Sussan Atifeh • *Not* Internal • Resolved

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.

Martha Meza
Email: martham@phfewic.org **Business:** (626) 856-6618

Catherine E Yepez, MPH
Email: catherinem@phfewic.org **Business:** 6268566650 xt271

Nelly Mallo, MS
Email: nelly@phfewic.org **Business:** (626) 856-6618 ext 245

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

False

Project Information

SUBMITTER

Application completed by:

Christopher Anderson, PhD, MSPH
Email: christophera@phfewic.org **Business:** (626) 430-4212

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).

Types Of Infant Formula And Infant Outcomes

PROJECT SITE

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

Public Health Foundation Enterprise (PHFE) WIC

STUDY PROCEDURES

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

Data Registry
Program Evaluations
Surveys

TYPE OF RESEARCH REQUEST

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

Please select "Information Practices Act" as well as "Common rule/Human subjects." Thank you!

05/12/2025 • 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)*

SB-13 (Information Practices Act)
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."

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

Checklist-For-Research-Involving-Children_revised-2-25-22.pdf	Children Supplemental Form

FUNDING

Is this research funded?

INTERNAL NOTE:

In the attached cover letter they explained:

The research team has applied for funding from the NIH and AHA. The NIH review was delayed and will now happen on May 14, 2025. They expect to get final funding decisions in early June. They assume they will get funding, but will update CPHS if anything changes.

05/08/2025 • Sussan Atifeh • Internal

Yes

Indicate the funding source for this project.
Federally funded
Privately funded

Enter name of federally-funded source.
National Institutes of Health

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

07/01/2025

ANTICIPATED PROJECT END DATE

06/30/2027

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.

Infant formula is associated with higher risk of child obesity compared to breastmilk, and lactose-reduced infant formula made with corn syrup solids (CSSFs) are associated with higher obesity risk compared to lactose-based infant formula. CSSFs have become very common among WIC participants in California, increasing from 20% of WIC-issued formula in 2014 to over 40% of WIC-issued formula in 2024. PHFE WIC will implement a policy change in 2025 that will involve 2 elements: 1) establishing a lactose-based infant formula as the default infant formula at first issuance to a participating infant (this is already encouraged by CDPH WIC policy, and requires some additional staff training), and 2) training WIC staff on the different composition of the contract infant formula types. The overall goal of the proposed project is to conduct an observational study comparing infants born, enrolled in WIC, and issued infant formula in the 3 months before and after the policy changes to identify whether these policy changes lead to lower lactose-reduced infant formula made with corn syrup solids (CSSF) issuance and healthier child diets and growth. This project will involve longitudinal data collection with the mothers of WIC-participating infants, with surveys, dietary recalls, and anthropometric measurement data collected at 3 and 9 months of age. This project will also involve longitudinal data collection with WIC staff, before and after the training on WIC issued infant formulas and PHFE WIC infant formula policy. All study activities will take place at PHFE WIC in Southern California. This project is expected to result in multiple peer reviewed publications and presentations at national conferences for WIC practitioners and academics.

MAJOR RESEARCH QUESTION

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

This study will address 3 major research questions:

Research Question 1: Does establishing a lactose-based default infant formula and a WIC staff educational program lead to increased WIC staff knowledge about infant formula type and formula issuance policies?

Research Question 2: Does establishing a lactose-based default infant formula and a WIC staff educational program lead to differences in the types of infant formula issued and consumed among WIC-participating formula fed infants?

Research question 3: Does establishing a lactose-based default infant formula and a WIC staff educational program lead to lower incidence of rapid infant weight gain among WIC-participating formula fed infants?

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

To ensure accurate review and processing of your application, could you please clarify whether any state data will be used to contact study participants? Specifically, please confirm whether state databases or records will be accessed to identify, recruit, or communicate with subjects. If no state data will be used for contact purposes, please state this clearly in the application.

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The overall objective of the proposed study is to identify the associations of the introduction of a new WIC policy establishing a lactose-based default infant formula issued by the program and the introduction of an educational program about infant formula type for WIC staff with 1) staff knowledge about infant formula type, 2) dietary behaviors among WIC-participating infants, and 3) rapid infant weight gain among WIC-participating infants. This will be accomplished at PHFE WIC with WIC staff and a longitudinal sample of WIC-enrolled infants issued infant formula by PHFE WIC. As part of standard professional development and educational activities, WIC staff will complete an assessment of knowledge about infant formula type and associations between infant formula type and child health outcomes before participating in an educational program about infant formula type; a second knowledge assessment will take place immediately following completion of the educational program, and a third assessment will take place at 1 year following completion of the educational program. This will allow the assessment of the whether the educational program for WIC staff is associated with changes in WIC staff knowledge about the associations between infant formula type and health outcomes, and whether these changes persist for at least 1 year. Longitudinal data on infant and child diet will be collected among infants enrolled in the 3 months before and the 3 months after the establishment of the lactose-based default infant formula issued by WIC and the introduction of the educational program for WIC staff on infant formula type (simultaneous introduction). Infant formula type preference is established early in infancy, and therefore comparing infants enrolled in the 3 months before and after the policy changes is expected to capture of the impact of the default formula policy and staff educational program. The study will determine whether there are associations between the default formula policy change and educational program with the type of infant formula issued to WIC-participating infants, with longitudinal assessments of infant and child diet, and with rapid infant weight gain. Data will include longitudinal WIC administrative data on infant formula issuance and redemption from 0-11 months of age, infant diet assessed with 24HRs

at 3 and 9 months of age, and child length and weight measured at 3 and 9 months of age. The establishment of a default infant formula type issued by WIC and the staff educational program about infant formula type will be evaluated as the exposure of interest, with comparison of infants born and enrolled in the 3 months prior to the policy changes and infants born and enrolled in the 3 months after the policy changes.

Infant component of the study:

Surveys and 24-hour dietary recalls: Infants eligible for inclusion in this aim will be identified using PHFE WIC administrative data collected when enrolling an infant in WIC. WIC administrative data including directory information (phone number(s), address of residence, name(s), and whether the household has elected to receive text message communication from WIC), infant characteristics (date of birth, issuance of infant formula), and maternal characteristics (language preference) will be used to identify infants eligible for inclusion in the study and in the recruitment of study participants. Spanish- and English-speaking caregivers who enroll an infant in WIC and have opted into receiving SMS communications from WIC will be invited to participate in the study at 1.5-2.5 months following delivery. At 3 months of age, invited caregivers will be sent a text message via PHFE WIC's secure computer-based interactive texting platform, and invited to complete an online survey and 24-hour dietary recall (24HR) for the infant. Diet will be assessed with the Automated Self-Administered 24-hour Dietary Assessment (ASA24), which performs well among low-income women, and is valid for proxy reporting of diet among young children by a parent. These caregivers will be asked to complete 1 additional survey, including an additional 24HR, at child age 9 months. The sample will include equal numbers of infants born and enrolled in WIC in the 3 months prior to and the 3 months after the establishment of the lactose-based infant formula default and the introduction of the educational program for WIC staff (pre- and post-policy change groups). Timing of the two surveys in each group (at 3 and 9 months of age) were selected to assess infant diet while all infants are anticipated to be receiving either breastmilk or infant formula both before (age 3 months) and after (age 9 months) the anticipated introduction of complementary foods and beverages, which has been reported to occur on average around 5 months of age in a nationally-representative WIC participant sample. Based on our research team experience collecting data among WIC participants in Southern California, we anticipate a 10% loss to follow-up among both pre-policy change and post-policy change groups in each successive survey; thus, baseline recruitment will be adjusted accordingly (i.e., we will interview n=1,320 [660 pre-policy change, 660 post-policy change], n=1,200 [600 pre and 600 post] respondents at child ages 3 and 9 months, respectively). A randomly-selected 10% sample at each time-point (n=132 and 120 at child ages 3 and 9 months, respectively) will be asked to provide a duplicate 24HR within 10-days of the initial 24HR to facilitate the estimation of usual dietary intakes for episodically consumed foods and beverages. Incentives will be provided to compensate participants for their time, and the amount will increase for the 9 month survey to maximize retention ($15 and $20/24HR at child ages 3 and 9 months, respectively). Longitudinal 24HRs and survey data, including the 18-item Household Food Security Survey Module (HFSSM), will be linked to WIC food

benefit issuance and redemption information from WIC administrative records.

Infant anthropometry: The same infants whose caregivers complete online surveys and telephone-based 24HRs (described above) will also be assessed for rapid infant weight gain. At 3 months of age, following the completion of the 24HR, the caregiver will be invited to provide a length and weight measurements for the study-participating infant. Participants will have two options for having anthropometric measures collected: by WIC staff at a WIC site, or by the child's healthcare provider with measures returned to research staff via a mailed anthropometry card (with return address and postage affixed). These cards will be mailed to the participants, and the child's healthcare provider can fill it out with the most recently measured length and weight for the child (and the date of the measurement) and return it via the mail. Additional incentives will be provided to participants for each set of anthropometric measurements ($10 and $10 provided at child ages 3 and 9 months, respectively). Longitudinal length or height and weight measurements will be linked to WIC food benefit issuance and redemption information from WIC administrative records.

Staff surveys: WIC staff from PHFE WIC will be eligible for inclusion in this assessment. All staff are fluent in English, and all training materials and data collection instruments will be produced in English. Before the 1-hour staff educational program module about WIC-issued infant formula types and the establishment of a default to lactose-based formula for newly enrolling infants, staff will complete a brief online knowledge assessment (Staff Survey 1). A knowledge assessment will be repeated in the week following the staff educational program (Staff Survey 2), with a final assessment conducted one year later (Staff Survey 3). These knowledge assessments will incorporate assessment of knowledge about the various infant formula types provided by the WIC program, including knowledge of the differences in composition of the types of infant formula, and the clinical indications for each type of infant formula (e.g. why an infant might need to receive a soy-based infant formula. Staff surveys will be linked using staff identifiers to facilitate the comparison of changes in knowledge for individual staff by staff characteristics.

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.

Age 3 month 24 hour recall (English)	Instruments
Age 3 months participant survey (English)	Instruments
Age 9 month participant survey (English)	Instruments
Age 9 months 24 hour recall (English)	Instruments
Baseline Staff Survey	Instruments
Follow-up Staff Survey	Instruments

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.

Can you please clarify in the "Procedures" section of the application whether you use WIC MIS data on benefit issuance and redemption data (that based on the table below, you requested from CDPH) for contacting any subjects in this study? Thanks.

05/09/2025 • Sussan Atifeh • *Not* Internal • Resolved

Agency	Provide the formal name of the data base or specimen registry.
California Department of Public Health	WIC MIS data on benefit issuance and redemption

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.

PHFE WIC Staff:
This prospective collection of surveys on knowledge about infant formula types will aim to include all WIC staff from a large local-agency Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) program in Southern California. This study will recruit WIC staff employed by Public Health Foundation Enterprises (PHFE) WIC in Southern California. Staff will be followed prospectively through surveys including an assessment of staff knowledge about infant formula types issued by the WIC program. A total sample of up to 500 staff will be recruited at baseline and complete a survey prior to the introduction of an educational program on infant formula type for WIC staff (survey 1). Staff are then anticipated to complete follow-up surveys immediately after (survey 2) and one-year after (survey 3) the introduction of an educational program on infant formula type for WIC staff . The WIC program in Southern California serves six primary groups defined by race, ethnicity, and language preference. The diversity of WIC staff mirrors the diversity of WIC participants. All WIC staff are fluent in English, and all data collection among WIC staff will be conducted in English. PHFE WIC staff are predominantly female, and are all adults of 18 years of age or greater.

WIC-participating infants:
This prospective collection of dietary recalls, food security, length and weight, and other covariate information from children ages 3-9 months from Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)-participating households in Southern California will attempt to recruit a diverse sample representative of WIC-participating households. This study will recruit postpartum women with an infant participating in and issued infant formula by Public Health Foundation Enterprises (PHFE) WIC in Southern California, between 1.5 and 2.5 months postpartum. Women who enroll their WIC-participating infants in the study will be followed prospectively through 2 surveys, inclusive of 24-hour dietary recalls and detailed household food security assessments, at child ages 3 months and 9 months. A total sample of 1,320 infants (660 for the group born and enrolled in WIC pre-introduction of policy changes, 660 for the group born and enrolled in WIC post-introduction of policy changes) will be recruited at baseline, with an anticipated 10% loss to follow-up between the two surveys (leaving a sample of 1,200 children at age 9 months (600 pre- and 600 post-introduction of policy changes)). The WIC program in Southern California serves six primary groups defined by race, ethnicity, and language preference. This study will recruit from English- or Spanish-speaking households and will enroll children regardless of race and ethnicity. It is anticipated that the six primary racial and ethnic groups served by WIC in Southern California will be represented, including English-speaking (EN)-

Hispanic, Spanish-speaking (SP)-Hispanic, non-Hispanic (NH)-Asian, NH-Black, NH-White, and NH-Other race/ethnicity. Two Hispanic groups are planned (EN and SP) due to the predominance of Hispanic ethnicity among WIC participants in Southern California. No restrictions will be made on the sex of infants, and we anticipate approximate balance between male and female participants.

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.

Please attach all lists of requested variables (using descriptive names) by attaching the formal data dictionaries in this 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:
Name of Variables: List the requested variables.
Justification: Provide a brief explanation justifying the request for each variable.
Usage of Variables: Explain how each variable will be used.

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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 the attachment.

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.

WIC administrative data elements.docx List of Variables

RATIONALE

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

PHFE WIC Staff: There is currently no information about staff knowledge about infant formula types, and whether this knowledge and staff characteristics contribute to the types of infant formula issued to participants. Therefore, it is critical to assess the knowledge of all WIC staff before training, whether the training improves staff knowledge, and whether this improved knowledge is associated with changes in the types of infant formula issued.

WIC-participating infants: WIC participants have high risk of child obesity, and receipt of infant formula and rapid infant weight gain are both strong risk factors for subsequent obesity. It is critical to understand whether small policy changes in WIC can decrease the issuance of specialty infant formulas that are associated with the highest risk of obesity.

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.

PHFE WIC Staff:
Recruitment of the WIC staff involved in this Aim will be done via a notice placed on the internal staff webpage for PHFE WIC, and via an email sent to all staff notifying staff about the upcoming educational program on infant formula type with a pre-training web-based knowledge assessment. Written informed consent will be obtained from staff before each knowledge assessment (pre-training Staff Survey 1, immediate post-training Staff Survey 2, 1-year after training Staff Survey 3).

WIC-participating Infants:
Recruitment will be done according to the following approach. Study-eligible infants will be identified on a monthly basis using WIC administrative data collected from participants upon enrollment in the program. At infant age 1.5 to 2.5 months, mothers of eligible infants will be sent a text message via PHFE WIC's secure interactive texting portal to make them aware of the study, with contact information for a project specialist in the WIC program who is available to answer any questions they may have about the study. At infant age 3 months, mothers of study-eligible infants will receive a text message from a WIC project specialist to offer them an opportunity to participate in the longitudinal study with data collections planned at infant ages 3 and 9 months.

Attach copies of all recruitment materials.

Recruitment Materials 05.02.2025.docx Recruitment Materials

SCREENING

Will subjects be screened prior to entry into the research?

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.
PHFE WIC Staff: No screening will be done. No information collected about individuals who do not enroll in the study will be retained by researchers.

WIC-participating infants: Infants from a household with a language preference other than English or Spanish will not be eligible for inclusion due to inadequate research staff proficiency to support data collection in other languages. Infants from a household that has not opted in to receiving text messages and phone calls from WIC will not be included in the study, as contacting them for recruitment will not be feasible. Infants born at less than 30 weeks gestation will not be included, as they exhibit different patterns of diet and growth due to the severe prematurity. No information collected about individuals who do not enroll in the study will be retained by the researchers.

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.
WIC-participating infants: Retention will be encouraged via the provision of incentives that increase with each successive data collection following the completion of each dietary recall ($15 at 3 months of age, $20 at 9 months of age). Incentives that increase with child age will also be provided to encourage retention. Incentives for anthropometry data will be provided following each collection of anthropometric data, either in a WIC site by WIC staff or by the child's healthcare provider and returned via mailed postcard ($10 at 3 months of age, $10 at 9 months of age).

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.

PHFE WIC staff: This is a two-year study. WIC staff will be asked to complete 3 surveys. Each survey will be approximately 10 minutes. Total approximate time commitment for WIC staff will be 0.5 hours.

WIC-participating infants: This is a two-year study. Participants will be asked to complete two surveys, two 24-hour dietary recalls, and 2 anthropometric data collections. Each survey will be approximately 30 minutes, each 24-hour dietary recall will be approximately 30 minutes, and each anthropometric data collection will be less than 15 minutes. Total approximate time commitment for WIC-participating infants/caregivers will be <2.5 hours.

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.

The level of risk is minimal. There are no anticipated risks to participants other than risks to confidentiality. The parent survey and 24-hour dietary recall reflect an expansion of questions already asked routinely in the WIC setting (food security and dietary screening) and is not expected to cause discomfort or embarrassment.

There are no anticipated risks to WIC staff other than risks to confidentiality. Knowledge assessments conducted among WIC staff are a standard part of WIC staff education, and are not expected to cause discomfort or embarrassment.

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 medical services will be provided as the study does not anticipate any adverse effects to result from the administration of the questionnaires and assessments.

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.

Not applicable.

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 are no direct benefits for participants for taking part in the research study. WIC participants at PHFE WIC who participate in the study will benefit by receiving incentives for each data collection ($15 for dietary recall at age 3 months, $10 for length/weight measurements at age 3 months; $20 for dietary recall at age 9 months, $10 for length/weight measurements at age 9 months). The study may benefit society by seeking to address a policy change that could substantially advance our knowledge about effective policies in nutrition assistance program to mitigate known risks for adverse child growth and obesity.

JUSTIFICATION OF RISKS

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

A rigorous evaluation of changes to WIC infant formula issuance policies and staff training is critical to demonstrate the impact of policy changes, if implemented more broadly, would have on reducing adverse diet and rapid infant weight gain among nutritionally at-risk infants. The minimal risks associated with study participation are reasonable considering the value of the information to be gained from the study.

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
Account number
No identifiable materials

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.

The principal investigator and co-investigator, both PHFE WIC staff, will have access to all study data (for both WIC-participating infants and WIC staff). Additional WIC staff members will have access to WIC participant information (surveys, dietary recalls, and anthropometry) due to their involvement in collecting the data. They are all PHFE WIC employees who received a background check upon hire and signed an institutional policy, as a condition of their employment, on confidentiality and protecting WIC participants' personal information. All research staff involved in the project have completed training on the protection of human subjects in research.

STAFF VETTING PROCEDURES

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

All PHFE WIC staff receive a background check prior to hire. Only existing PHFE WIC staff will have access to PID.

SUPPORT LETTER

Obtain and submit a department support/data release letter.

> Thank you for providing the support letter. To ensure it aligns with the acceptable format specified on the CPHS website, could you please update the wording to include "and federal" in the section below?
>
> ...that any release of personal information to the principal investigator will be in compliance with all applicable state "and federal" statutes.
>
> 05/08/2025 • 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.

PHFE formula study letter of support_updated.pdf	Department Letter of Support

Deleted Attachments: 1 (Most Recent: PHFE formula study letter of support.pdf on 05/09/2025 9:49 AM 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.

Study participants will be assigned a unique and anonymous identifier, and will be tracked using that number for analytic purposes. The online surveys, 24 hour dietary recalls, and anthropometric data will be collected via online survey, on the phone with WIC staff, and in WIC centers (or via mail from a healthcare provider). All data will be collected for the study by WIC staff. No paper forms will be generated. All digital information will be stored on PHFE WIC's firewall protected server, and accessible only through approved password protected devices. All identifying information will be removed from the final analytic datasets by WIC staff and replaced by a study ID to create an anonymized data file for analysis.

CONFIDENTIALITY OF PUBLISHED DATA

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

We will not publish any information that could possibly be used to identify an individual subject.

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 necessary data to perform the research.

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.

Only research staff will be granted access to the data and only PHFE WIC employees who have signed a confidentiality agreement will have access to PID.

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.

Because of the large sample size, we believe it is unlikely that we will encounter small cells or small numbers. We will not release or publish individual or record-level data; data will only be presented and/or published as summarized data to reduce risk of potential re-identification of de-identified individuals. Although we believe that cell sizes won't be small enough to put us at risk for re-identification AND there are no plans to release the data, whenever possible, we will opt for the conservative approach of applying statistical masking methods to ensure our data is adequately de-identified.

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.
The only datasets that will be linked are the selected elements from the CDPH WIC WISE (management information system) dataset for the infants who are enrolled in the study, to allow complete analysis of the survey, 24 hour recall, and anthropometric data collected from participants. Data elements to be drawn from the CDPH WIC WISE include directory information, relevant sociodemographic characteristics for characterizing the study sample, relevant dates (birth, benefit issuance, anthropometric measurement), infant formula issuance and redemption, and any child anthropometric measurements.

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.
No answer provided.

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*

Letter from See K 4 30 25.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 be de-identified

Explain what identifiers will be removed and how.
Randomly-generated study-specific identifiers will be generated for the study. Following the completion and linking of study data for study participants across all data collections, participant identifiers (dates of birth, WIC individual identifiers, WIC family identifiers, residential addresses, contact information including phone number and email) will be removed from the final analytic dataset, and only the randomly-generated study-specific identifiers (allowing the linking of individual responses across each data collection, but precluding reidentification of the participant) will be retained.

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 that will need to be destroyed at the end of the study, as all data collection will be electronic. Anthropometric measurement cards, which will not contain any PID (only randomly-generated study IDs), returned to WIC will be destroyed by cross cut shredding after data entry.

FAXING

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

Not applicable, as not faxing will be used in the study.

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.

Mailings of anthropometric measurement cards from PHFE WIC to participants will be done on a weekly basis. It is anticipated that each mailing will consist of <100 cards, mailed in individual envelopes via USPS. Cards will contain no PID, but the randomly-generated study identifier, so will not reveal any PID when returned using USPS by the child's healthcare provider.

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.

No PID will be collected in paper format for this study. Anthropometric measurement cards will contain only unique study IDs.

The electronic PID will be only accessible from password protected workstations within the internal network and will be removed from the analytic dataset. The PID will not be stored on laptop computers or portable electronic storage media.

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.

No PID will be stored in paper form. The electronic PID will be only accessible from password protected workstations within the internal network, which has controlled access procedures, and 24 hour guard and monitored alarm service.

SERVER SECURITY

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

All servers containing unencrypted PID are housed in a secure room with controlled access procedures.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

Identifiers will be stored separately from analysis data.

DISK STORAGE

State whether all disks with PID will be destroyed.

The PID will not be stored on disks, but PID will be destroyed at the conclusion of the study.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

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

All computer access is password protected.

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 contain PID have full disc encryption that uses FIPS 140-2 compliant software.

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.

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.

Not applicable.

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.

All workstations have security patches applied in a reasonable timeframe.

PASSWORD CONTROLS

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

Strong password comparisons are in place to protect PID stored on workstations, laptops, servers, and removable media.

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.

Sufficient system security comparisons 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.

The PID will be only used on the encrypted server and will not be used outside the secure internal network.

INTERNET ACCESSIBILITY

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

PID 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.

When disposing of electronic PID, sufficiently secure wiping will be used.

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.

An informed consent waiver is requested as this study is being conducted by PHFE WIC, in partnership with CDPH WIC. The study is designed to assess the impact of possible changes in the WIC infant formula policy on infant outcomes (Criteria A). In addition, this study involves no more than minimal risk to the subjects, the waiver will not adversely affect the rights and welfare of the subjects and, when appropriate, the subjects will be provided with additional information about the study at its close (Criteria B). All questions on the caregiver questionnaire are an enhancement of routine questions that participants are asked during their WIC visits, and the CDPH WIC and PHFE WIC study teams are the only staff who will have access to participant information.

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 Script 05.02.2025.docx Consent Form

TRANSLATED DOCUMENTS

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

Consent Script SPANISH 05.02.2025.docx Consent Form

Deleted Attachments: 1 (Most Recent: Spanish on 05/02/2025 12:57 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.

C Yepez CV Translator Curriculum Vitae

Informed Consent Waiver

INFORMED CONSENT WAIVER

Are you requesting a waiver or alteration of informed consent?

Yes

Provide a rationale as to why the research could not practicably be conducted without the waiver or alteration.
Collecting informed consent from participants would increase the burden to WIC participants and staff, in that it would require WIC staff to schedule phone calls with participants to read the consent script and collect oral informed consent, or it would require the processing and mailing of consent scripts to participants for signature and return via mail. This burden in staff time and postage would necessitate a severe reduction in the sample size for the proposed study, and preclude collecting adequate data to draw valid conclusions about the impact of the policy changes. Furthermore, it is likely that either process (oral or written) for documenting informed consent would lead to a respondent sample that is less representative of WIC participants served by PHFE WIC (caregivers who possibly have higher educational attainment and are more health conscious), which might mean that the study findings are not generalizable to all WIC-participating formula fed infants, which is the critical component of this study.

Provide a detailed account of the plans and measures that will be in place to protect the rights and welfare of the subjects.
WIC participants being recruited for inclusion in the study will be provided with information about the purpose of the study, the anticipated data collections (and time commitment of each), and the incentives. Information about how to reach research staff for answering individual questions will be provided. Further, this information will all clearly communicate that participation in the research is voluntary, that participation (or election not to participate) will in no way alter the WIC benefits provided to the individual/family, and that if they choose to enroll they are free to withdraw from the study at any point with no consequences for their WIC participation status.

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?

> Please attach a copy of the project's budget when ready. Thanks.
>
> 05/08/2025 • Sussan Atifeh • *Not* Internal • Resolved

Yes

Attach a copy of your project budget here

Infant Formula Type and Infant Outcomes Study Budget (planned).doc	Project Budget

Deleted Attachments: 1 (Most Recent: R01_CSSF_BUDGET JUSTIFICATION.doc on 05/09/2025 9:47 AM ET)

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

IRB Cover Letter Anderson_FINAL_05.02.2025.docx	Cover Letter

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 Monday, May 12, 2025 4:34:54 PM ET by Christopher Anderson, PhD, MSPH

In order to submit this form, click "Next" and "Submit." At that time, the application will be routed to the Responsible Official (if this is the first submission) for review and signature.

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

California Department of Public Health: WIC MIS data on benefit issuance and redemption

Responsible Official Signature
- Submitted 05/02/2025 1:14 PM ET by Kiran Saluja, MPH, RD

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, May 2, 2025 1:14:05 PM ET by Kiran Saluja, MPH, RD

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 05/12/2025 6:04 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
Researchers from Public Health Foundation Enterprise WIC have submitted this application to request approval for a project with Human Subjects' Contacts (HSC).

• PHFE WIC is changing its infant formula policy in 2025 to make lactose-based formula the default and to train staff on formula differences. Researchers will compare babies before and after the change to see if it leads to less use of corn syrup-based formula and healthier growth. Data will be collected from mothers and WIC staff, with findings shared in academic journals and national conferences. The study wants to see how two changes at PHFE WIC affect infant diet and weight gain:
1. Making lactose-based formula the default option for new WIC participants.
2. Training WIC staff about different formula types.

• Data Providing Department: They have requested WIC MIS data on benefit issuance and redemption
from CDPH.

Choose the CPHS Chair
Catherine Hess, PhD

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

Assign to Cycle

June

Assign to cycle year
2025

Load into IRBManager (Initial Submission)
- Submitted 05/12/2025 6:04 PM ET by The System

Chair Review and Full Board Set-Up
- Submitted 05/15/2025 7:07 PM ET by Sussan Atifeh

Full Board Set Up

Project number

2025-067

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
Researchers from Public Health Foundation Enterprise WIC have submitted this application to request approval for a project with Human Subjects' Contacts (HSC).

• PHFE WIC is changing its infant formula policy in 2025 to make lactose-based formula the default and to train staff on formula differences. Researchers will compare babies before and after the change to see if it leads to less use of corn syrup-based formula and healthier growth. Data will be collected from mothers and WIC staff, with findings shared in academic journals and national conferences. The study wants to see how two changes at PHFE WIC affect infant diet and weight gain:
1. Making lactose-based formula the default option for new WIC participants.
2. Training WIC staff about different formula types.

• Data Providing Department: They have requested WIC MIS data on benefit issuance and redemption from CDPH.

Assign SME to study

Jonni Johnson, PhD

Enter the meeting date for this project

06/06/2025

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.