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 11/10/2025 8:02 PM ET by Shannon Whaley, PhD

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

December 2025 cycle.

_____Full Board HSC New Project_____

**********Non-English translations should be reviewed after the approval of the English versions**********

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11/07/2025 • Sussan Atifeh • Internal

Researchers from the Public Health Foundation Enterprise (PHFE) WIC and CDPH have submitted this application to request approval for a project with human subjects' contacts involvements. On April 20, 2026, the next round of changes to the WIC packages will be implemented in California and the CDPH and PHFE WIC teams have designed a longitudinal evaluation to document the impacts of the these changes on California WIC participants' behaviors. Researchers plan to survey a random sample of 20,000 WIC-enrolled families before and after the change. Surveys will be sent via text in English or Spanish, with participants receiving a $10 gift card for each completed survey. The study includes baseline data collection in early 2026 and follow-up in early 2027, targeting 4,000 completed responses. Researchers will also use administrative WIC data to analyze participation, benefit use, and demographics, ensuring a representative sample and linking survey responses to program engagement.

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

• Data-Source Department:
CDPH (WIC WISE data)—A LOS from CDPH is attached.

• Funding:
Federally funded—National Institute of Food and Agriculture (NIFA) provides partial funding

• Linkage:
Yes—The only datasets that will be linked to survey data collected from study participants are the selected elements from the CDPH WIC WISE (management information system) dataset for the families sampled. Data elements to be drawn from the CDPH WIC WISE include:
• Participation data (monthly for each individual)
• Redemption data (monthly subcategory level benefit redemption for the individual's household)
• Demographics (participant sex, race, ethnicity, date of birth; caregiver language preference, educational attainment; household residential address, income, size; Medicaid, TANF participation)

• End products:
Include (1) a summary report for internal use that informs CDPH decision-making around California's food package, (2) dissemination of key findings through public webinars and conferences, and (3) at least three peer-reviewed publications based on the work.

11/07/2025 • Sussan Atifeh • Internal

Dear Researchers: Please check all pages of the application (scroll down to see the entire page), address the comment(s), and resubmit the application. This project will be scheduled to be discussed in the CPHS December 5, 2025, full board meeting. Thanks,

11/07/2025 • 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.

Shannon Whaley, PhD

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

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.

Shannon E Whaley 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.

No answer provided.

ADMINISTRATIVE CONTACT

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

Catherine E Yepez, MPH

Email: catherinem@phfewic.org **Business:** 6268566650 xt271

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.*

Denise Gee, MPH, RDN

Email: Denise@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.

11/07/2025 • Sussan Atifeh • *Not* Internal

Dear Researchers: The list below, provided by you, includes CDPH research staff who will have access to the data in this study and should be listed in this section as research staff. As noted in your recent email, you are currently working on gathering their information in order to create IRBManager accounts for them.

Ms. Margaret Demment
Ms. Susan Sabatier
Mr. Jakeem Lewis
Mr. Adrian Young
Ms. Jessica Dunn
Ms. Michaela DeBolt
Ms. Lindsey Partington
Ms. Yoshie Shih
Ms. Megan Long
Mr. Levi Evans

When the application is next returned to data entry by the SME reviewer, please be sure to list these individuals in this section as research staff by creating their accounts in IRBManager. If they already have an account in IRBManager, you can simply add them in this section.

Thanks.

11/10/2025 • Sussan Atifeh • *Not* Internal

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

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

Meg Demment, PhD
Email: Meg.Demment@cdph.ca.gov **Business:** (518) 867-5225

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

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

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

False

Project Information

SUBMITTER

Application completed by:

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

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).

Evaluation of the 2026 WIC Food Package Changes

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.

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

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

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

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

Thanks.

11/07/2025 • Sussan Atifeh • *Not* Internal • Resolved

Data Registry
Program Evaluations
Recruitment-Participant
Specimen Registry
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."

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.

Pregnant Women and Fetuses

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

Link to Pregnant Women and Fetuses Supplemental Form

Pregnant Women Supplement Form - not required for survey research	Pregnant Women and Fetuses Supplemental Form

FUNDING

Is this research funded?

Yes

Indicate the funding source for this project.
Federally funded

Enter name of federally-funded source.
NIFA provides partial funding

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

01/12/2026

ANTICIPATED PROJECT END DATE

12/31/2028

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.

Please name the main site of the project in this section.

• Note:
The main site(s) of the study is/are the institution(s) responsible for the primary storage, receipt, management of study data, and accountable for ensuring data security and compliance with relevant regulations, including overseeing access controls, data encryption, and privacy safeguards—typically PI's institution, which is housing the servers through which the data is processed.

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From 2008-2010, the CDPH WIC and PHFE WIC programs conducted the most thorough evaluation in the country of the 2009 WIC food package changes, results from which have impacted ongoing WIC food package policy. On April 20, 2026, the next round of changes to the WIC packages will be implemented in California and the CDPH and PHFE WIC teams have designed a longitudinal evaluation to document the impacts of the these changes on California WIC participants' behaviors. A substantial amount of data on redemption and participation can be gathered through existing administrative WIC data without additional data collection efforts, but additional data collection through surveys of a random sample of California WIC participants is needed to understand the impacts of this landmark change on food intake and diet quality, total household food expenditures on food, and ease of/barriers to purchasing the new foods. A random sample of 20,000 California WIC participants will be selected in January 2026, with a sample of ~4,000 expected to complete an online survey in February-March 2026, prior to the food package change on April 20 (Time 1 – baseline). One year later, respondents to the baseline survey will be invited to complete a post-change follow-up survey (Time 2 – post-change follow-up, N~2000). Data used for this study will include both survey data, as described above, and California WIC administrative data. All members of the evaluation team are employees of either CDPH WIC or PHFE WIC. The main site of the study is PHFE WIC.

The aims of this project are to document the impact of the 2026 food package changes on California WIC participant (1) redemption of WIC foods (administrative data), (2) ongoing participation in WIC in California (administrative data), (3) food intake and diet quality (survey data), (4) food security (survey data), (5) food purchasing (survey data), and (6) perceptions of the food package (survey data). The expected end products include (1) a summary report for internal use that informs CDPH decision-making around California's food package, (2) dissemination of key findings through public webinars and conferences, and (3) at least three peer-reviewed publications based on the work.

MAJOR RESEARCH QUESTION

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

What is the impact of the 2026 WIC food package (FP) changes on California WIC participant redemption of WIC foods, ongoing participation in WIC in California, food intake and diet quality, food security, food purchasing, and perceptions of the food package.

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

The overall objective of the proposed study is to identify the impacts of the April 2026 changes to the WIC food package. This will be accomplished with a longitudinal design at two points in time, before and after the food package change implementation, with a random sample of WIC-enrolled households with a child age <3.5 years and/or a pregnant or post-partum woman participating in the program. In January 2026, CDPH WIC staff will draw a random sample of 20,000 participants who meet the eligibility criteria from the population of all families served by the California WIC program. These families will be texted a survey link by CDPH WIC staff in February-March 2026 using the CDPH WIC Teletask (TT) system, a secure computer-based interactive texting system that has been in place to serve California WIC families for over 5 years. We are estimating a 20% response rate based on our prior survey research with this population, however we will divide the sample into three batches so as to minimize participant burden should response rates be higher than expected. A first batch of 10,000 texts will go out in early February 2026, at which time a response rate can be determined. Two additional batches of 5,000 each will be sent out as needed in February and March to reach a final sample size of 4,000 completed surveys. Every week after the first batch of texts are sent, a roster of families who have not responded to the survey invitation will be developed; families who have not responded will receive up to three reminder texts with the survey link, at intervals of no less than 1 week apart. Families will be sent a survey link in either English or Spanish, based on their preferred language for WIC services. All families who complete a baseline survey will receive an electronic gift card in the amount of $10.

The survey is expected to take 30 minutes or less and the following language will be sent in the text:

Share your thoughts about WIC foods and shopping in a 30-min survey. Receive a $10 gift card. It's voluntary and will not affect your WIC benefits. You can skip any questions. Take the survey [LINK HERE].

Comparta su opinión acerca de los alimentos de WIC y sus experiencias con las compras de WIC en una encuesta de 30 minutos. Recibirá una tarjeta de regalo de $10. Es voluntario, no afectara sus beneficios de WIC. Puedes omitir cualquier pregunta. Responda a la encuesta [LINK HERE].

In order to examine the impacts of the food package change, one year later (February-March 2027) all ~4000 participants who completed the baseline survey will receive the follow-up survey. The same texting protocol will be utilized, with surveys texted to each family, and up to three reminder texts sent to non-responders. We anticipate at least 2000 families to complete the follow-up survey, all of whom will receive an additional electronic gift card in the amount of $10.

The following administrative data from the California WIC WISE system, already collected as part of routine WIC service delivery, is needed for the 20,000 randomly selected families for the period from October 2025-June 2028:
• Participation data (monthly for each individual)
• Redemption data (monthly subcategory level benefit redemption for the individual's household)
• Demographics (participant sex, race, ethnicity, date of birth; caregiver language preference, educational attainment; household residential address, income, size; Medicaid, TANF participation)

These data will be gathered by the CDPH WIC team and shared with the PHFE WIC team so that administrative data can be linked to survey data for the 4000 respondents. Administrative data is needed also for the non-respondents in order to ensure the demographic composition of the respondents represents that of the population (and, if not, to control for group differences).

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.

2025 WIC FP CHANGE Survey - ENGLISH 10.31.2025.docx Questionnaires
2025 WIC FP CHANGE Survey - SPANISH 10.31.2025.docx Questionnaires

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.

CDPH: Department of Public Health

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	WIC WISE

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.

California WIC currently serves ~715,000 families with WIC's healthy foods, nutrition education, breastfeeding support and referrals to health and social services. WIC participants are pregnant and postpartum women up to 12 months postpartum, infants and children up to age 5 who are income-eligible (<185% of the Federal Poverty Level) and have a nutrition risk. Over 98% of California's WIC participants speak English or Spanish. A similarly large percentage have opted in to receiving texts from WIC and receive texts regularly from CDPH WIC and/or their local agency WIC program.

To be eligible to be drawn into the random sample of 20,000 participants, the primary caregiver must speak English or Spanish and be at least 18 years of age. At least one member of the household – a pregnant or postpartum woman, infant and/or child 6 to 42 months of age - must be an active certified participant as of January 2026. WIC participating households whose only WIC participant(s) is a child older than 42 months are excluded due to them aging out of WIC prior to the follow-up survey in February-March 2027. Households with only a foster child(ren) participating in WIC will also be excluded due to the higher likelihood of them changing households in the year between survey waves.

CDPH staff will draw a random sample of 20,000 participants, batched into three groups (10k; 5k; 5k), in order to reach a sample of 4000 households at baseline (February-March, 2026). After the first batch of 10,000 is recruited, should response rates be higher than 20%, calibration may be done on the remaining sample such that not all 20,000 families receive an initial invitation to participate. At the follow-up (February-March 2027), the 4000 households who completed the baseline survey will be texted the follow-up survey link for an expected final follow-up sample of ~2000 households.

Respondents are expected to be the primary caregiver, usually the mother, who is the primary contact for the WIC family and will be the recipient of the survey link via text. If only one member of the family is receiving WIC benefits, that family member will be the target of all questions related to food intake. If more than one member of the family is receiving WIC benefits, the first section of the survey asks about all members receiving WIC and then selects ONE member of the household as the target for food intake questions. If the respondent is not the member who does the food shopping for the family, a substantial portion of the survey is skipped, but that family remains eligible to complete the survey.

The survey is programmed in Survey Monkey such that it cannot be forwarded to another person for completion, thereby reducing potential for non-sampled individuals to complete the survey. A unique and randomly generated code will be assigned to each survey to link that survey to a family's WIC ID, which is only accessible by CDPH and PHFE WIC employees.

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.

The WIC administrative data elements that will be used to assess the impact of the WIC food package change on participant outcomes including redemption, participation, and diet are detailed in the attachment. Using WIC administrative data from the CDPH WIC WISE system is necessary to evaluate the proposed policy changes, and will minimize participant burden by using administrative data elements (and therefore not taking additional time from participants to collect these data elements as part of a survey for the study). All research staff to be involved in this study are PHFE WIC or CDPH WIC employees who have access WIC administrative data to allow them to perform their job functions. All variables used to describe the sample will be presented in aggregate (e.g. as a frequency and percent or as a mean and standard deviation) to avoid presenting any data that represents only an individual, and WIC administrative data elements marked with an asterisk (*) will be removed from the de-identified analytic dataset.

Also attached is the list of all CDPH WIC employees who may have access to the data during this project. The department head, Meg Demment, is included as a contact in this submission. These are the members of her team who may be involved in this project.

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.

CDPH Research Staff.xlsx	List of Variables
WIC administrative data elements_11.07.2025.docx	List of Variables

RATIONALE

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

This study aims to evaluate the impact of the WIC food package change on a representative sample of WIC households across California. The only reason for excluding older children on WIC (>42 months of age) and foster children is that they may no longer be eligible for WIC or in the same household in March 2027, the time of the follow-up survey.

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.

CDPH staff will draw a random sample of 20,000 participants, batched into three groups (10k; 5k; 5k), in order to reach a sample of 4000 households at baseline (February-March, 2026). Participants will be recruited via text through the California WIC Teletask texting system. After the first batch of 10,000 is recruited, should response rates be higher than 20%, calibration may be done on the remaining sample such that not all 20,000 families receive an initial invitation to participate. At the follow-up (February-March 2027), the 4000 households who completed the baseline survey will be texted the follow-up survey link for an expected final follow-up sample of ~2000 households.

Attach copies of all recruitment materials.

Recruitment Materials.docx Recruitment Materials

Deleted Attachments: 1 (Most Recent: Recruitment Materials PLACEHOLDER.docx on 11/05/2025 6:28 PM ET)

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.
To be eligible to be drawn into the random sample of 20,000 participants, the primary caregiver must speak English or Spanish and be at least 18 years of age. At least one member of the household – a pregnant or postpartum woman, infant and/or child 6 to 42 months of age - must be an active certified participant as of January 2026. WIC participating households whose only WIC participant(s) is a child older than 42 months or is a foster child are excluded due to them aging out of WIC prior to the follow-up survey or potentially moving households by February-March 2027.

Information available to CDPH WIC study staff on all 20,000 participants includes the following:
• Participation data (monthly for each individual)
• Redemption data (monthly subcategory level benefit redemption for the individual's household)
• Demographics (participant sex, race, ethnicity, date of birth; caregiver language preference, educational attainment; household residential address, income, size; Medicaid, TANF participation)

These information will be collected for all individuals in the random sample for recruitment, including non-respondents. Data on non-respondents will be stripped of identifiers, and summarized for the non-respondent group as a whole for the purposes of comparing the baseline characteristics of the respondent and non-respondent groups.

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.
A gift card in the amount of $10 will be sent electronically upon completion of the survey.

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.

This is a 3 year study (January 2026-December 2028). Active data collection will take place in two surveys conducted in February-March of 2026 (survey 1) and February-March 2027 (survey 2). Each survey is anticipated to take less than 30 minutes to complete. Administrative data will be captured through June 2028 to assess patterns of redemption and program participation. Total approximate time commitment for participants is 1 hour.

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 survey questions reflect an expansion of similar questions asked routinely in the WIC setting (food security and dietary screening) 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 an online survey.

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.

This study presents less than minimal risk for study participants.

BENEFITS

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

There is no direct benefit anticipated for the study participants other than being offered an incentive.

JUSTIFICATION OF RISKS

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

The risks of any physical, psychological and social harm for participants are very minimal while the results from this study will help to improve the WIC services which may benefit all WIC participating families including the study participants.

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

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-investigators, all of whom are PHFE or CDPH WIC staff, will have access to all study data. Additional WIC staff members will have access to WIC participant information due to their involvement in collecting the data, sending electronic gift cards, and/or responding to study-related inquiries from caregivers during recruitment. All study staff are PHFE WIC or CDPH 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 and CDPH WIC staff receive a background check prior to hire. Only existing PHFE and CDPH WIC staff will have access to PID.

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.

PHFE__Eval of 2026 Food Package Changes CPHS letter of support .pdf Department Letter of Support

Deleted Attachments: 1 (Most Recent: CDPH Letter PLACEHOLDER.docx on 10/31/2025 7:58 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.

Study participants will be assigned a unique and randomly generated (anonymous) identifier, and will be tracked using that number for analytic purposes. All new data will be collected via online survey. All data will only be accessed by WIC staff. All digital information will be stored on CDPH and PHFE WIC's firewall protected servers, 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 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 apply statistical masking methods to ensure our data is adequately de-identified, such as recategorizing variables to suppress the presentation of cell sizes of fewer than 11 individuals.

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 to survey data collected from study participants are the selected elements from the CDPH WIC WISE (management information system) dataset for the families sampled. Data elements to be drawn from the CDPH WIC WISE include:
• Participation data (monthly for each individual)
• Redemption data (monthly subcategory level benefit redemption for the individual's household)
• Demographics (participant sex, race, ethnicity, date of birth; caregiver language preference, educational attainment; household residential address, income, size; Medicaid, TANF participation)

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*

DataSecurity_CK_FPC_2025.pdf Data Security Letter

Deleted Attachments: 2 (Most Recent: Data Security Letter PLACEHOLDER.docx on 11/05/2025 6:35 PM ET)

Physical Safeguards

DATA PROTECTION

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

Yes

DATA DESTRUCTION

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

Yes

RETAINED DATA

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

data will 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.

FAXING

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

Not applicable.

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.

Not applicable.

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. All study data will be collected via online survey. 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 outsidethe 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.

A waiver of informed consent is requested as this study is being conducted by staff at CDPH and PHFE WIC to evaluate the WIC program. The study is designed to assess the impact of changes to the WIC food package on participants (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 online 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. The survey introduction also includes the attached language prior to commencing the survey (See Consent script attachments).

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 English.docx Consent Form

Deleted Attachments: 1 (Most Recent: Consent forms PLACEHOLDER.docx on 11/05/2025 6:41 PM ET)

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.docx Consent Form

Deleted Attachments: 1 (Most Recent: Translated consent forms PLACEHOLDER.docx on 11/05/2025 6:41 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.

Cat_Yepez_WorkCV.docx.pdf Translator Curriculum Vitae

Deleted Attachments: 1 (Most Recent: Translator letter PLACEHOLDER.docx on 11/05/2025 6:45 PM ET)

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.
Prior to commencing the online survey, we have included information about the background and purpose of this study. Participants will be presented with this information before any data collection takes place, and will be provided with contact information to seek additional information about the study as part of the recruitment and consent processes (please see script in previous response and in the survey instrument itself). Collecting informed consent via mailed physical form or orally via telephone is not feasible for this evaluation, and would lead to a respondent sample that is less representative of California WIC participants (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 families, which is a critical component of this study. Only if a participant agrees to participate in the study (expressing interest in response to recruitment materials and responding affirmatively after being presented with consent materials) will they be enrolled in the 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), the potential risks of participation, 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?

Yes

Attach a copy of your project budget here
Incentives Budget.docx Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

Cover Letter.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, November 10, 2025 8:02:51 PM ET by Shannon Whaley, PhD

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 WISE

Responsible Official Signature
- Submitted 11/06/2025 9:46 PM ET by Denise Gee, MPH, RDN

Responsible Official Signature

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

Yes, ready for submission to IRB.

Enter your password to sign this protocol. By signing this protocol, you are attesting that the information within is accurate and reflects the details of the proposed research project.
Signed Thursday, November 6, 2025 9:43:49 PM ET by Denise Gee, MPH, RDN

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 11/10/2025 8:57 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
The Chairs confirmed this project should be discussed in the December 5 full board meeting due to human subjects' contacts components.

Choose the CPHS Chair
Catherine Hess, PhD

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

Assign to Cycle

December

Assign to cycle year
2025

Load into IRBManager (Initial Submission)
- Submitted 11/10/2025 8:58 PM ET by The System

Chair Review and Full Board Set-Up
- Submitted 11/10/2025 8:59 PM ET by Sussan Atifeh

Full Board Set Up

Project number

2025-177

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
The Chairs confirmed this project should be discussed in the December 5 full board meeting due to human subjects' contacts components.

Assign SME to study

Maria Ventura, PhD

Enter the meeting date for this project

12/05/2025

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.