

University of California, Davis
Institutional Review Board
Initial Review Application

Last edited by: Marisa Tsai
Last edited on: May 18, 2020

[\[click for checklist\]](#)

[1599428-1] COVID-19: Documenting Challenges Faced by California Families with Children 0-5 Years Old on WIC

I. Personnel Information

Principal Investigator:

Name: Lorrene Ritchie, PhD, RD
Title: Director and Cooperative Extension Specialist **Degrees:** PhD, RD
Phone: (510) 642-3589 **Email:** Iritchie@ucanr.edu
Dept: Ag & Resource Economics

Will the person be involved in the consent process? Yes No

Co-Principal Investigator:

Name: ,
Title: **Phone:**
Dept: Public Health Foundation Enterprise (PHFE) WIC **Email:**

Will the person be involved in the consent process? Yes No

Primary Contact (if other than PI):

Name: Marisa Tsai
Phone: (510) 642-3589 **Email:** mmtsai@ucanr.edu

Will the person be involved in the consent process? Yes No

Additional Personnel:

Name: Nicole Vital, MA **Title:** Project Manager

Will the person be involved in the consent process? Yes No

Is this person a sub-investigator? Yes No

Additional Personnel:

Name: Kaela Plank, MS, MPH **Title:** Analyst

Will the person be involved in the consent process? Yes No

Is this person a sub-investigator? Yes No

Additional Personnel:

Name: Hallie Randel-Schreiber, MPH **Title:** Data collector
Will the person be involved in the consent process? Yes No
Is this person a sub-investigator? Yes No

Additional Personnel:

Name: Ron Stolic, MS **Title:** Data collector
Will the person be involved in the consent process? Yes No
Is this person a sub-investigator? Yes No

Additional Personnel:

Name: Claudia Olague, n/a **Title:** Translator
Will the person be involved in the consent process? Yes No
Is this person a sub-investigator? Yes No

Do any personnel have a related financial interest? Yes No
Financial interest disclosure forms been submitted? Yes No
Any actual or perceived conflict of interest? Yes No

II. Review Information

Are you relying on an IRB other than the UC Davis IRB? Yes No
Are any external sites relying on the UC Davis IRB? Yes No
Is this review part of the UC Reliance? Yes No
Reliance Number:

III. Relying on Other IRB Project InformationN/A

Author of Protocol: **Clinical Trial:**
of Participants: **Local Participants:**
Research Supported by CTSC? Yes No
Bill visits or procedures using Epic EMR? Yes No
Is there an IND for this project? Yes No
Number:
Holder:
Is there an IDE for this project? Yes No
Number:
Holder:

IV. General Project Information

N/A

Author of Protocol:

- UC Davis Researcher Cooperative Group
 Researcher from another institution Private Sponsor

This study involves or includes:

- Cancer patients or their data
 Radiation
 Stem cells
 rDNA Molecules, Human Gene Transfer, infectious agents, or biohazardous material
 Patient care services billed in the UC Davis Health System
 The analysis of coded and linked biological samples
 The analysis of completely anonymous biological samples
 Access, collection or use of identifiable health information
 Prospectively assign human subjects to one or more interventions
 Evaluate the effects of an intervention on health-related outcomes

Has this study previously been reviewed by an IRB? Yes No

Explanation:

Is this research investigator-initiated? Yes No

Is this research supported by the UC Davis CTSC? Yes No

Will this study be monitored for compliance? Yes No

Does your study bill visits or procedures using Epic EMR? Yes No

How will research be monitored for safety?

- Medical Monitor
 Data Safety Monitoring Committee
 Not Applicable/Minimal Risk

Please describe your monitoring plan.

V. Funding Information

N/A

Funding Source:

- Other:
 Federal Grant
 Other Grant
 Department Funded
 Industry Sponsored:

Please complete this section for each federal or other grant.

Title: COVID-19: Documenting Challenges Faced by California Families with Children 0-5 Years Old on WIC **ID Number:** Y20-5097

Sponsor: The David & Lucile Packard Foundation **Status:** Funded

Federal Funding:

- Yes
- No

VI. Location Information

N/A

Research Setting:

The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) is a federal nutrition assistance program for women, infants and children which provides nutrition education, referral to additional health services, and healthy food to low-income families with nutritional risk. The purpose of this project is to understand how participants are dealing with WIC appointments and services now that all moved remotely as well as to understand unmet needs during the COVID crisis faced by vulnerable families.

All research will be conducted remotely. Staff from Public Health Foundation Enterprises-WIC (PHFE WIC), a local WIC clinic and study partner, will pull a random sample of 500 WIC participants with children on WIC who are between the ages of 0 to 5 years old from the clinic administrative data. From that list, PHFE WIC will recruit and consent participants for the study over text or phone. PHFE WIC staff will send the first name and number of consented WIC participants to NPI. To protect participants, no identifying information will be shared with NPI. PHFE WIC will obtain IRB approval from the California Health and Human Services Agency Committee for the Protection of Human Subjects (CPHS) prior to any recruitment and consent activities.

Then, NPI staff will contact consented WIC participants to set up a time to administer the interview over the phone. At the designated time, an NPI researcher will call the participant and conduct the interview over the phone in English or Spanish, depending on participant preference, and ask for permission for the interviews to be audio recorded. Interview questions will be programmed into Qualtrics and interviewer-administered. If the participant completes the interview or interview time has exceeded 1 hour, gift cards will be sent by email, text, or mail as compensation. NPI will conduct up to 100 interviews.

Resources Available:

Staff

The principal investigator will oversee all project activities and NPI staff and ensure timely deliverables. She has had extensive experience in leading studies on the WIC program and its impact on feeding practices and food insecurity.

The project manager will assist with all project activities; she will also conduct phone interviews with English-speaking WIC participants and assist with qualitative data analyses. She has had experience leading several public health nutrition projects prior.

The data collectors will conduct phone interviews with English and Spanish-speaking WIC participants and WIC agency directors. All data collectors have previous experience during interviews with research participants and will be trained for this survey prior to administration. Data collectors conducting interviews in Spanish will be fluent in Spanish.

The translator is a native Spanish speaker and will conduct Spanish translations, transcribe and enter data from all recorded interviews, and order and mail gift cards to WIC participants.

The data analyst will create the data entry program and calculate descriptive statistics.

All research team members are CITI-certified.

Resources

Staff will use audio recorders, phones, and laptops to contact subjects and track participation.

PHFE WIC will contact up to 200 WIC participants and NPI will conduct interviews with approximately 50 participants.

- Is this a multi-site study? Yes No
- Is UC Davis the coordinating center? N/A Yes No
- Is this an international study? Yes No

Methods to comply with international conduct of research requirements:

- Are external sites being used? Yes No

Please complete this section for each external site.

Site Name	Contact Name	Contact Email
Public Health Foundation Enterprises WIC	Shannon Whaley	Shannon@phfewic.org

VII. Consent Information N/A

- Use of written or verbal screening scripts prior to consent? Yes No
- Follow HRP-090 and HRP-091 when obtaining consent? Yes No

If no, please explain:

The study partner, PHFE WIC (a WIC clinic) will obtain consent from their participants to 1) participate in the study and 2) allow PHFE WIC to share their first name and phone number with NPI.

Upon receiving the information, NPI will contact the consented participant to conduct the interview via phone. At the start of the interview, NPI will ask the participant if they consent to participate in the interview. This research is being conducted remotely due to COVID-19 restrictions.

Enrolling participants unable to speak or read English? Yes No

How will you (1) conduct the consent discussion in a language understandable to the participant; (2) conduct ongoing communication with the participant throughout the research and in case of emergency?

- At least one member of the research team is fluent in the language that will be used for communication and will be available during emergencies;
- The research team has 24-hour access to a translation service with sufficient medical expertise to discuss the research in this study;
- Other:
- N/A (only enrolling English speakers and readers)

Will consent form be translated into a language the participant(s) understand?

- Yes
- No
- N/A (only enrolling English speakers and readers)

Which of the following are involved?

- A written consent form signed by study participants
- IRB waiver of the requirements for a signed consent form.
- IRB approved waiver of consent

If "IRB waiver of the requirements for a signed consent form," answer the following questions:

Explain how this research only involves minimal risk:

This study is being conducted by NPI, in partnership with PHFE WIC and the California Department of Public Health WIC division, and is designed to study the impact of COVID-19-related challenges on WIC families. The research will not ask for any information that could place an individual at risk or criminal or civil liability or could be damaging to the participants' financial standing, employability or reputation. This study involves no more than minimal risk to the subjects and the waiver will not adversely affect the rights and welfare of the subjects.

The process of the study is as follows: PHFE WIC will recruit and secure consent from participants without involvement by NPI. PHFE WIC will invite a sample of their participants to participate in a research study, provide a description of the study procedure, and explain that participation is voluntary. The co-investigator is part of PHFE WIC and participants would have their contact information. Once participants consent to the study and agree for PHFE WIC to share their first names and numbers with NPI, PHFE WIC will send the first names and numbers of consented participants to NPI. NPI will not have any access to identifying information of participants. At that time, NPI will reach out to the participant to schedule an interview. At the start of the interview, the NPI research will verbally confirm with the participant that they consent to participate.

Research involve procedures which require written consent? Yes No

Is the participant's confidentiality the only risk? Yes No

Consent only document linking participant to research? Yes No

If "IRB approved waiver of consent," answer the following questions:

Is this research regulated by the FDA? Yes No

Please explain how this research only involves minimal risk:

Please explain how waiving consent does not adversely affect the participants' rights:

Explain why this research cannot be conducted without this waiver:

VIII. Participant Information

N/A

What is the anticipated number of participants to be enrolled in this study?

Study-Wide: 500

Locally: 500

Vulnerable Participants:

- | | |
|--|--|
| <input type="checkbox"/> Children | <input type="checkbox"/> Pregnant Women/Fetuses |
| <input type="checkbox"/> Neonates | <input type="checkbox"/> Cognitively Impaired Adults |
| <input type="checkbox"/> Prisoners | <input type="checkbox"/> Employees of UC Davis |
| <input type="checkbox"/> Students of the principal investigator,
justification: | <input checked="" type="checkbox"/> None |

Will participants receive payment for participation in this research?

- Participants will be compensated for their time.
- Participants will be reimbursed for their expenses.
- Participants will not be compensated or reimbursed.

Total Compensation: Participants will receive a \$25 gift card for Target if they complete the interview or the interview has taken over 1 hour.

Compensation Pro-ration: Compensation will not be pro-rated.

Compensation Distribution: Participants will be compensated in the form of a Target giftcard and will have the option to choose between email, text, or mail delivery. Participants will be sent their gift card soon after the interview.

Recruitment Information:

- | | |
|--|---|
| <input type="checkbox"/> Advertising | <input type="checkbox"/> Medical record review |
| <input type="checkbox"/> Referrals | <input type="checkbox"/> Clinical Trials Websites |
| <input type="checkbox"/> Internet | <input type="checkbox"/> Social Media |
| <input type="checkbox"/> From personal contact (i.e. patients, former research participants, friends, etc.) | |
| <input checked="" type="checkbox"/> From a database of participants who have given prior permission to be contacted for research studies | |
| <input type="checkbox"/> Other: | |

How will you comply with the HIPAA requirements?

- Signed HIPAA Research Authorization from the participant or the participant's legally authorized representative
- HIPAA Waiver of Authorization for participant identification and recruitment
- HIPAA Waiver of Authorization for the study
- Not applicable, I am not using identifiable health information for my study

Does the use or disclosure of PHI involve no more than a minimal risk to the privacy of the individual based on at least the presence of the following:

- I confirm that only authorized persons will be granted access to the identifiers; identifiers stored on computers, electronic notebooks, mobile devices, and/or data-storage devices will be encrypted and password protected; identifiers maintained in paper format will be kept in a locked area with access limited to only research staff who require access to conduct the study.
- I confirm that I will destroy the identifiers at the earliest opportunity consistent with the conduct of the research unless there is a health or research justification for retaining the identifiers or as otherwise required by law.
- I confirm that protected health information from this research will not be reused or disclosed to another person or entity, except as required by law, for authorized oversight of the research study, or other research for which the use or disclosure of PHI would be permitted.
- I confirm that I will use Quick Disclosure Activity in EMR to track all medical records accessed as defined by [P&P 2446](#)

Please list the specific elements of health information for which you are requesting the wavier.

What specific information will this waiver cover and why do you need this wavier to be able to conduct the research?

IX. Children Participant Information N/A

Category of Research for Children

- Minimal Risk Research
- Greater than Minimal Risk with prospect of direct benefit
- Greater than Minimal Risk with no prospect of direct benefit

Parental Permission will be obtained from:

- Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child
- One parent (or legal guardian)
- Neither parent (nor guardian) as this research meets the requirement for a waiver of consent

Assent from Children:

- Assent will be obtained from all children capable of assenting
- Assent will not be obtained from children who are too young to understand the research

- Assent will not be obtained from children because this research meets the requirements for a waiver of consent
- Assent will be documented by the person obtaining assent on the consent document
- Children who can read will be given an Information Sheet about the study

Describe children from whom assent will not be obtained and provide justification:

If "Minimal Risk Research," answer the following question:

Explain how this research presents no more than minimal risk to children:

If "Greater than Minimal Risk with prospect of direct benefit," answer the following questions:

Explain how this research involves greater than minimal risk:

Explain how the research presents the prospect of direct benefit to the children:

Explain how the risk is justified by the anticipated benefit:

Explain how the relation of the anticipated benefit to risk is at least as favorable as alternatives:

If "Greater than Minimal Risk with no prospect of direct benefit," answer the following questions:

Explain how this research involves a minor increase over minimal risk:

Explain how intervention presents experiences commensurate with actual/expected situations:

Explain how the intervention or procedure is likely to yield generalizable knowledge:

X. Cognitively Impaired Adult Participant Information

N/A

Describe your process for determining whether an adult has capacity to consent.

Will you follow California requirements for surrogate consent?

- Yes
- No

Will assent be obtained from all adults who lack capacity to consent & are capable of assenting?

- Yes

No

Will you obtain consent from the participant when s/he regains capacity?

Yes

No

XI. Drugs, Biologic and Dietary Supplements

N/A

Clinical Trial Phase:

This is not a clinical trial

Phase I

Phase I/II

Phase II

Phase II/III

Phase III

Phase IV

Please complete this section for each drug, biologic or dietary supplement.

Name:

Generic Name:

Is this drug approved by the FDA?

Yes

No

Will the results be reported to FDA for new indication/labelling change?

Yes

No

N/A

Will the results be used to support a significant change in advertising?

Yes

No

N/A

Does the proposal use significantly increases the risks of drug involved?

Yes

No

N/A

Please explain your answer regarding risk:

Do you have an IND number?

Yes

No

IND Number:

Holder of IND:

XII. Devices

N/A

Please complete this section for each device.

Device Name:

Do you have an IDE/HDE? Yes No N/A

IDE/HDE Number:

Holder of IDE:

Is this device exempt from the requirement for an IDE? Yes No N/A

Is the device approved by the FDA? Yes No

Is this device a Humanitarian Use Device (HUD)? Yes No

Is this device being used according to its approved label? Yes No N/A

If this device is not exempt from the requirement for an IDE and is not approved by the FDA (or if it is approved but is not being used according to its approved label) and you do not have an IDE number please select one of the following:

- N/A
- This device is a significant risk device (SR) (If you choose SR, you will need an IDE to conduct this study)
- This device is a non-significant risk device (NSR), justification:

XIII. Tissue Banking N/A

Collection Method:

Storage location:

Storage duration:

Ones with access:

Will identifiers be stored with specimens? Yes No

Will any identifiers be coded and linked to the individual? Yes No

Will any identifiable data be stored with the specimens? Yes No

XIV. Data Confidentiality

I confirm that only authorized persons will be granted access to the identifiers; identifiers stored on computers, electronic notebooks, mobile devices, and/or data-storage devices will be encrypted and password protected; identifiers maintained in paper format will be kept in a locked area with access limited only to research staff who require access to conduct the study.

- Yes
- No

XV. PI Attestation N/A

I attest, as the PI, that all personnel assigned to this study are qualified to perform the protocol procedures assigned to them, have completed required CITI/NIH training, have reported any and all conflicts of interest to the UC Davis Conflict of Interest Committee, and have received appropriate training on the protocol.

- Yes
- No

Additional Documents and Requirements

[\[top\]](#)

Thank you for completing this application form. Please review it for accuracy and obtain the necessary signatures. By submitting this application, the PI agrees to comply with all IRB and protocol requirements listed in HRP-103.

Please upload the following additional documentation in the IRBNet Designer:

- HRP-226 Administrative Approval
- HRP-503 Protocol for use with IRBNet Initial Review Application/ HRP-503 Record/Data Review Template for use with IRBNet Initial Review Application/ Sponsor Protocol
- Questionnaires/Surveys/Interview Questions (if applicable)
- Consent Script or Information Sheet