

INSTRUCTIONS FOR RESEARCH INVOLVING SURVEYS/INTERVIEWS AND/OR FOCUS GROUPS: use in conjunction with the online Initial Review Application form when no sponsor authored protocol is available.

1) Objectives

Purpose: To increase COVID-19 vaccination among Latino/Hispano populations in Yolo, Madera, Fresno, and Stanislaus counties in California by improving awareness about the benefits of the COVID-19 vaccine and in the process learn about the barriers to vaccination in the communities.

Objectives:

- i) Conduct focus groups and implement a survey among Latino/Hispano community members of the counties of interest to learn about factors (barriers and facilitators) that contribute to their decision of getting vaccinated for COVID-19.

2) Background

The COVID-19 pandemic disproportionately affected Latina/o communities throughout the U.S. Although California has experienced lower COVID-19 mortality relative to other states, Latinas/os in the state are overrepresented in cumulative cases (3,784 versus 1,112 per 100K) and deaths (59.2 versus 38.3 per 100K) and are underrepresented in testing (35,635 versus 48,930 per 100K), than White (non-Latina/o); they are also 8.1 times more likely to live in high-exposure risk households. The rates of the primary series completion (not including booster) for Whites is 68.5% compared to 59.5% among Latinos. COVID-19 disparities can be attributed to a complex interplay of factors that arise from structural racism, from structured inequities in income and wealth, to high-risk occupations, high-exposure-risk households and housing conditions, cultural, linguistic, temporal and geographic barriers in access to testing and vaccination. The overall objective of this study is to identify barriers and facilitators to COVID-19 vaccination across a diversity of Latino/a populations in Yolo, Madera, Fresno, and Stanislaus Counties in California.

3) Indicate the procedures that you will use to collect data.

☒ **Surveys – Attach all surveys you will use in this study.**

☐ **Interviews – Attach an interview script with the questions that will be asked during the interview.**

☒ **Focus groups – Attach a summary of the questions and issues that will be discussed during the focus sessions.**

☐ **Observation of public behavior – Describe the behavior you will be observing below.**

☐ **Other – Describe any other data collection or research procedures you will be conducting**

4) Will you record any information that directly or indirectly identifies the individual on the data collection form (survey, interview responses or documentation of observations)?

☒ Yes – Provide justification for recording identifiers. In other words, why do you need to record the identifiers?

First name, last name, address, email, phone number, and age in years will be needed for scheduling and providing compensation.

☐ No

Responses obtained from only the following will include direct or indirect identifiers:

Click here to enter text.

5) Participants' will be:

☒ Audiotaped

☐ Videotaped

Recordings will be labeled with direct or indirect identifiers: ☐ Yes ☒ No

6) Data Management and Confidentiality

Before completing this section, see [Privacy and Confidentiality](#) and [HIPAA Guidance](#).

- a) List any identifiers that will be collected during the course of this study (e.g., name, medical record number, date of birth, video recordings, etc.):

First name, last name, address, email, phone number, and age in years will be collected.

- b) If any identifiers will be stored, how long will they be kept?

Until the completion of data collection.

- c) For data that is coded with a linking key, at what point will the linking key be destroyed?

Until the completion of data collection.

- d) For any recordings, at what point will the recordings be destroyed?

Two years after the completion of data collection.

7) Inclusion and Exclusion Criteria

Inclusion Criteria:

1. Participants must be Hispanic/Latino, meaning a person of Latin American origin in the U.S.
2. Participants must live within four counties in California: Yolo, Stanislaus, Madera, and Fresno.
3. Participant must be 18 years of age or older

Exclusion Criteria:

1. Participants not of Hispanic/Latino decent, and not living the in the counties listed above will be excluded in this study.
2. Participants under the age of 18 years will not be included in this study.

8) Study Timelines

The duration anticipated to enroll all study subjects for prospective data collection only:

- ☒ I will be enrolling subjects until: We have collected 300 surveys completed
- i. In the first month we will work with community partners to recruit participants for the survey and focus groups.
 - ii. By the second month, we will continue to disseminate surveys and start our first set of focus groups.
 - iii. In Month 3, we will continue to disseminate our surveys and star our second set of focus groups.

The estimated date for the investigators to complete this study (complete primary analyses):

We estimate the study will be completed by the end of March of 2023.

9) Data Banking

Will data be banked for future use? ☒ Yes ☐ No

☐ Yes, the data will be identifiable

☒ No, the data will be completely anonymous.

☐ No, the data will be stripped of identifiers and will be coded.

Where will the data be stored?

Data collected will not be identifiable and will be kept as confidential with utmost attention to security via locked documents, secured computers, and locked cabinet storage.

How long will the data be stored?

Data will be stored in a locked cabinet and secure computer documents for an estimated storage of 2-3 years.

Who will have access to the data?

Only the Principal Investigator and research assistants will have access to the data collected.

Describe the procedures to release data, including: the process to request a release, approvals required for release and who can obtain data.

Survey data will be released and disseminated once it has been harmonized and analyzed. No Identifiable data will be released with findings.

10) Risks to Subjects

☒ This data collection study poses minimal risk of loss of confidentiality. The risk

will be minimized through the processes described above. This study will abide by all applicable law, regulations, and standard operating governing the protection of human subjects, student information and protected health information.

☐ Other – Describe: [Click here to enter text.](#)

11) Potential Benefits to Subjects

☒ There is no direct benefit to participants of the focus groups or surveys.

☐ Other – Describe: [Click here to enter text.](#)

12) Sharing of Results with Subjects

☐ Results will not be shared with subjects.

☒ Results will be shared with subjects – Describe: If they choose to sign up to receive information, updates and newsletters from the research team, participants can provide their name, phone number and email for a listserv/mailling list.

13) Review Requirement

Are there any contractual obligations or other considerations that require IRB review of this research, or review at intervals other than those required by the Common Rule or FDA? If yes, check box:

☐ Yes

☒ No