COVID-19 Vaccination Take-Up in a Medicaid Managed Care Population

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Manual of Procedures (MOP)
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Table of Contents

1.0 INTRODUCTION **3**
2.0 BRIEF OVERVIEW OF THE STUDY PROTOCOL **3**
3.0 STUDY STAFF RESPONSIBILITIES **3**
4.0 STUDY FLOW DIAGRAM **4**
Figure 1: Study Flow Diagram 4
5.0 RECRUITMENT AND RETENTION **4**
5.1 Screening and Eligibility Criteria 5
5.2 Screening Log 5
5.3 ELIGIBILITY CRITERIA **5**
6.0 INFORMED CONSENT **5**
6.1 HIPAA Authorization 5
7.0 STUDY INTERVENTION **5**
8.0 RANDOMIZATION **5**
9.0 BLINDING AND UNBLINDING (MASKING AND UNMASKING) **8**
10.0 SAFETY REPORTING **8**
11.0 STUDY COMPLIANCE **8**
12.0 DATA COLLECTION AND STUDY FORMS **9**
12.1 Participant Data 9
12.2 Study Forms 9
12.3 General Instructions for Completing Forms 9
12.4 Data Flow 9
12.5 Administrative Forms 9
12.6 Retention of Study Documentation 9
13.0 DATA MANAGEMENT **9**
13.1 External Data 9
13.2 Quality Control Procedures 9
14.0 CONCOMITANT MEDICATIONS **9**
15.0 DATA AND SAFETY MONITORING ACTIVITIES **10**
15.1 Study Completion and Close-Out Procedures 10
15.1.1 Participant Notification *10*
15.1.2 Confidentiality Procedures *10*
16.0 MOP MAINTENANCE **10**
APPENDIX A: IRB-APPROVED STUDY PROTOCOL **12**
APPENDIX B: INFORMED CONSENT DOCUMENTS AND HIPAA AUTHORIZATION **50**
APPENDIX C: MOP MODIFICATIONS LOG **69**

1.0 Introduction

We will measure COVID-19 related preventative health behaviors, including COVID-19 vaccinations, in the Contra Costa County, CA Medicaid managed care population. Our goal is to test ways to increase COVID-19 vaccination uptake. Our hypothesis is that as a result of financial, cultural, or access issues, among other things, vaccinations and other preventative health behaviors are too low from a public health standpoint, meaning relative to virus exposure and the potential adverse consequences of infection in low-income and racial/ethnic minority populations. Furthermore, we hypothesize that small financial incentives and other low-cost behavioral nudges can be used to reduce disparities, increasing vaccination rates and other behaviors known to mitigate the spread of the virus.

2.0 Brief Overview of the Study Protocol

Approximately 10,000 adult subjects will be recruited from the Contra Costa Health Plan (CCHP) via baseline survey. Subjects who complete the baseline survey will be randomized to the following arms:

1. Control Arm (n=2,500)
2. Informational Arm: no information/emotional message vs. safety and effectiveness information vs. information on consequences of going unvaccinated, race and/or gender concordant or discordant [7,500]

Each of these arms will be interacted with a financial incentive of $10 (N=2,500) or $50 (N=2,500) and, separately with a convenient link to the county public vaccine appointment scheduling system highlighted for participants (N=5,000).

The above treatments are designed to test the role of the following on vaccine take-up:

- Financial incentives [N=5,000] vs. no financial incentives [N=5,000]
    - 2,500 will be randomized to a $10 incentive and 2,500 to a $50 incentive
- Convenient scheduling link highlighted [N=5,000] vs. not [N=5,000]
- Messaging [N=7,500] vs not [2,500]
    - Message type: emotion [N=2,500] vs. safety and effectiveness [N=2,500] vs. consequences of not vaccinating [N=2,500]
- Race concordant [N=2,500] vs. race discordant messenger [N=2,500]
- Gender concordant [N=2,500] vs. gender discordant messenger [N=2,500]

We will obtain survey data on preventative health behaviors, including mask-wearing, hand washing, and willingness to vaccinate. We will obtain EMR data on vaccine take-up.

3.0 Study Staff Responsibilities

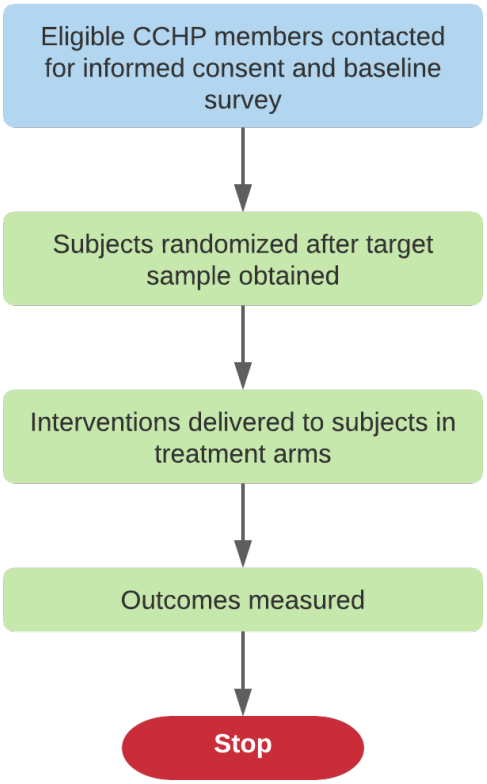
Pilot PI Jacobson will have ultimate responsibility for the study's design and implementation. She will be supported by Other Significant Contributors Tom Chang and Manisha Shah. Jacobson will develop all study materials, including this MOP. She will be

responsible for monitoring and reporting adverse events (AEs), serious adverse events (SAEs), and other issues per the terms of the relevant Data and Safety Monitoring Plan (DSMP). She will obtain informed consent and HIPAA authorization from all subjects; recruit and randomize subjects; receive EMR data from CCHS; following the procedures in this MOP and the IRB-approved protocol; and report any protocol deviations to the IRB and other relevant parties. She will be responsible for protecting subjects' rights on a daily basis. She will oversee all data management procedures and quality control procedures.

Collaborator Rajiv Pramanik of Conta Costa Health System (CCHS) will facilitate subject contacts and sharing of EMR data. CCHS will provide data on eligible CCHP members and will be responsible for screening members for eligibility.

4.0 Study Flow Diagram

Figure 1: Study Flow Diagram



5.0 Recruitment and Retention

A random sample of eligible CCHP members will be invited to participate in the study via email, mail, and/or text. We aim to recruit 10,000 subjects and recruitment will continue until we have reached 10,000 baseline survey responses.

We will provide gift cards for baseline survey completion ($5 or $25, depending on survey take-up). In addition, respondents will be entered into a raffle for $250 gift cards.

5.1 Screening and Eligibility Criteria

CCHS will provide a list of eligible members and will be responsible for eligibility screening. Pilot PI Jacobson will not be responsible for eligibility screening. See 5.3 for Eligibility Criteria.

5.2 Screening Log

As screening will not be performed by Pilot PI Jacobson or her academic study team, this group will not maintain a screening log. Collaborator Pramanik will maintain documentation of eligibility determinations.

5.3 Eligibility Criteria

Eligible subjects are adult CCHP members with no previous COVID-19 vaccination history and no contraindications to COVID-19 vaccination, as determined in CCHP medical staff.

6.0 Informed Consent

Informed consent will be obtained during the baseline survey to recruit subjects. The IRB-approved consent documents are attached as an appendix.

6.1 HIPAA Authorization

Personal health information (PHI) will be obtained in keeping with the Health Insurance Portability and Accountability Act (HIPAA). The IRB approved a partial HIPAA waiver for purposes of study participant recruitment. The study outcome, COVID-19 vaccination, is PHI. The IRB-approved HIPAA authorization form is attached as an appendix.

7.0 Study Intervention

Subjects in treatment arms will receive interventions:

- Financial incentives [N=5,000] vs. no financial incentives [N=5,000]
    - 2,500 will be randomized to a $10 incentive and 2,500 to a $50 incentive
- Convenient scheduling link highlighted [N=5,000] vs. not [N=5,000]
- Messaging [N=7,500] vs not [2,500]
    - Message type: emotion [N=2,500] vs. safety and effectiveness [N=2,500] vs. consequences of not vaccinating [N=2,500]
- Race concordant [N=2,500] vs. race discordant messenger [N=2,500]
- Gender concordant [N=2,500] vs. gender discordant messenger [N=2,500]

8.0 Randomization

We will stratify our sample based on based on race/ethnicity and age-group. Randomization will be performed in the RedCAP system. In practice, the randomization will divide the sample into 60 possible conditions:

1. Control [N=625]
2. Control x $10 financial [N=312.5]
3. Control x $50 financial [N=312.5]

4. Control x link [N=625]
5. Control x $10 financial x link [N=312.5]
6. Control x $50 financial x link [N=312.5]
7. No information/Emotional (language concordant) [N=625]
8. No information/Emotional (language concordant) x $10 financial [N=312.5]
9. No information/Emotional (language concordant) x $50 financial [N=312.5]
10. No information/Emotional (language concordant) x link [N=625]
11. No information/Emotional (language concordant) x $10 financial x link [N=312.5]
12. No information/Emotional (language concordant) x $50 financial x link [N=312.5]
13. Safety and effectiveness (race concordant, male) [N=156.25]
14. Safety and effectiveness (race concordant, male) x $10 financial incentive [N=78.125]
15. Safety and effectiveness (race concordant, male) x $50 financial incentive [N=78.125]
16. Safety and effectiveness (race concordant, male) x link [N=156.25]
17. Safety and effectiveness (race concordant, male) x $10 financial incentive [N=78.125]
18. Safety and effectiveness (race concordant, male) x $50 financial incentive [N=78.125]
19. Safety and effectiveness (race concordant, female) [N=156.25]
20. Safety and effectiveness (race concordant, female) x $10 financial incentive [N=78.125]
21. Safety and effectiveness (race concordant, female) x $50 financial incentive [N=78.125]
22. Safety and effectiveness (race concordant, female) x link [N=156.25]
23. Safety and effectiveness (race concordant, female) x $10 financial incentive x link [N=78.125]
24. Safety and effectiveness (race concordant, female) x $50 financial incentive x link [N=78.125]
25. Safety and effectiveness (race discordant, male) [N=156.25]
26. Safety and effectiveness (race discordant, male) x $10 financial incentive [N=78.125]
27. Safety and effectiveness (race discordant, male) x $50 financial incentive [N=78.125]
28. Safety and effectiveness (race discordant, male) x link [N=156.25]
29. Safety and effectiveness (race discordant, male) x financial incentive x link [N=78.125]
30. Safety and effectiveness (race discordant, male) x financial incentive x link [N=78.125]
31. Safety and effectiveness (race discordant, female) [N=156.25]
32. Safety and effectiveness (race discordant, female) x $10 financial incentive [N=78.125]

33. Safety and effectiveness (race discordant, female) x $50 financial incentive [N=78.125]
34. Safety and effectiveness (race discordant, female) x link [N=156.25]
35. Safety and effectiveness (race discordant, female) x $10 financial incentive x link [N=78.125]
36. Safety and effectiveness (race discordant, female) x $50 financial incentive x link [N=78.125]
37. Consequences of going unvaccinated (race concordant, male) [N=156.25]
38. Consequences of going unvaccinated (race concordant, male) x $10 financial incentive [N=78.125]
39. Consequences of going unvaccinated (race concordant, male) x $50 financial incentive [N=78.125]
40. Consequences of going unvaccinated (race concordant, male) x link [N=156.25]
41. Consequences of going unvaccinated (race concordant, male) x $10 financial incentive x link [N=78.125]
42. Consequences of going unvaccinated (race concordant, male) x $50 financial incentive x link [N=78.125]
43. Consequences of going unvaccinated (race concordant, female) [N=156.25]
44. Consequences of going unvaccinated (race concordant, female) x $10 financial incentive [N=78.125]
45. Consequences of going unvaccinated (race concordant, female) x $50 financial incentive [N=78.125]
46. Consequences of going unvaccinated (race concordant, female) x link [N=156.25]
47. Consequences of going unvaccinated (race concordant, female) x $10 financial incentive x link [N=78.125]
48. Consequences of going unvaccinated (race concordant, female) x $50 financial incentive x link [N=78.125]
49. Consequences of going unvaccinated (race discordant, male) [N=156.25]
50. Consequences of going unvaccinated (race discordant, male) x $10 financial incentive [N=78.125]
51. Consequences of going unvaccinated (race discordant, male) x $50 financial incentive [N=78.125]
52. Consequences of going unvaccinated (race discordant, male) x link [N=156.25]
53. Consequences of going unvaccinated (race discordant, male) x $10 financial incentive x link [N=78.125]
54. Consequences of going unvaccinated (race discordant, male) x $50 financial incentive x link [N=78.125]
55. Consequences of going unvaccinated (race discordant, female) [N=156.25]
56. Consequences of going unvaccinated (race discordant, female) x $10 financial incentive [N=78.125]
57. Consequences of going unvaccinated (race discordant, female) x $50 financial incentive [N=78.125]

58. Consequences of going unvaccinated (race discordant, male) x link [N=156.25]
59. Consequences of going unvaccinated (race discordant, male) x $10 financial incentive x link [N=78.125]
60. Consequences of going unvaccinated (race discordant, male) x $50 financial incentive x link [N=78.125]

Randomization assignments will be documented for future reference.

9.0 Blinding and Unblinding (Masking and Unmasking)

There is no scope for masking in this study. Subjects will know that treatment they have received, if any. We will not mask care providers or outcomes assessors.

10.0 Safety Reporting

Per our DSMP, we will be unable to observe AEs and SAEs in our survey and EMR data.

Routine monitoring of EMR data for AEs and SAEs will not be conducted.

However, if the research team becomes aware through other channels of a specific event, the report will immediately be relayed to the PIs.

The PI will determine whether the event constitutes an AE or SAE, and classify any AEs or SAEs on their severity, expectedness, and relatedness, as above. The PI will consult with a qualified clinician as necessary to make such determinations. Affected subjects will be advised to visit a local, qualified medical practitioner.

Unexpected SAEs will be reported to the Safety Officer (SO), IRB, and NIA within 48 hours of the study's knowledge, and summarized in periodic electronic reports to the SO.

Any unanticipated problem, defined as an issue related to the research that suggests the research places participants or others at greater risk than was expected, will be reported to NIA and the SO within 48 hours of the study's knowledge. Reporting will occur within 24 hours if the problem involves death. The report will include a plan to correct the problem and prevent its reoccurrence.

Any SAEs related to the study and any unanticipated problems will also be promptly reported to the sIRB.

11.0 Study Compliance

Protocol deviations for this study, while exceedingly unlikely, could include randomizing an ineligible participant; obtaining incomplete or inadequate informed consent; administering the wrong treatment to a subject; or failing to keep the IRB protocol up to date.

Any deviations that impact participant safety will be reported to NIA and the SO within 24 hours of occurrence, or as soon as they are discovered. All other deviations will be

captured in routine reports to NIA and the SO. All deviations will be reported to the sIRB of Record in accordance with local policies and captured in the protocol deviations log in the appendix of this MOP.

12.0 Data Collection and Study Forms

12.1 Participant Data

Individual-level survey data, EMR data, and randomization information will be maintained electronically by the study team. Survey data will be received directly by the study team. EMR data will be transmitted from CCHS to the study team.

12.2 Study Forms

There are no study-specific forms for this study.

12.3 General Instructions for Completing Forms

Not applicable.

12.4 Data Flow

Data, which will include PHI, will be stored on secure servers only available to the research team. Coded data will be used for analysis and will be stored separately from the identifiable data.

12.5 Administrative Forms

We will use the Adverse Event Form and Serious Adverse Event Form from the NIA Clinical Research Study Investigator's Toolbox to record any AEs or SAEs.

12.6 Retention of Study Documentation

Participant data will be retained by the study team for at least the NIH minimum of three years. We have no plans for data destruction at this time. Informed consent will be included in the baseline survey data and maintained indefinitely.

13.0 Data Management

13.1 External Data

The study team will receive data from CCHS on eligible CCHP members and on enrolled subjects' vaccine outcomes. These data transfers will rely on Box.com, which encrypts the data during transfer and at rest. USC and CCHS will execute appropriate data use agreement(s) before transferring any data.

13.2 Quality Control Procedures

The study team will review data from CCHS, as well as survey data, as soon as possible after receipt. The team will perform standard data quality checks, to include flagging missing, out-of-range, or illogical data.

14.0 Concomitant Medications

Not applicable.

15.0 Data and Safety Monitoring Activities

15.1 Study Completion and Close-Out Procedures

At close-out, Pilot PI Jacobson will ensure that all required data has been received and that all data and analysis files are organized and accessible for review. She will ensure that all required study information has been reported to the NIA and other funders. She will notify the IRB of Record of the study's completion and retain a copy of this notification. Finally, she will prepare a report summarizing the study's conduct.

15.1.1 Participant Notification

We do not plan to notify subjects or their health providers of the results of the study.

15.1.2 Confidentiality Procedures

Data will be stored securely as described in 12.4 and 13.1 above. Data will be accessed only by staff with a legitimate need. All staff will be properly trained in human subjects research practices and appropriately supervised.

If computers are used to store and/or analyze clinical data, the investigator should address elements of computer security to ensure that the data remain confidential. These elements include but are not limited to: utilization of computer and system passwords, user security training, system testing and verification, and routine system backups to prevent any loss of electronic data.

16.0 MOP Maintenance

Each page of the MOP is numbered, dated, and includes a version number. Modifications are logged in the appendix.

APPENDIX A: IRB-Approved Study Protocol and 06/01/2021 Amendment

Version: 1.4
Application Version Date: 4/28/2021

1. Project Identification and Abstract

1.1. * **Type of Submission**:

- (●) **Research Protocol or Study on Human Subjects**
- ( ) Grant/Contract Only
- ( ) Use of Humanitarian Use Device (Not Research)
- ( ) Rely on another IRB (Ceded)

1.2. * **Full Title of Research Protocol**
COVID-19 and Preventive Health Behaviors in at-Risk Medicaid Populations

1.3. * **Short Title**
COVID-19 and Preventive Health Behaviors

1.4. **Abstract: Provide a simple explanation of the study and briefly address (in 1 to 2 sentences) each of the following points: rationale; intervention; objectives or purpose; study population or sample characteristics; study methodology; description of study arms (if appropriate); study endpoints or outcomes; follow-up; statistics and plans for analysis.**
In this work, we are partnering with Contra Costa Health Services (CCHS), the department of health in Contra Costa County, CA, to measure COVID-19 related preventive health behaviors, including COVID-19 vaccinations, in the county's Medicaid managed care population and test ways to increase COVID-19 vaccine uptake. Our hypothesis is that, as a result of financial, cultural or access issues, among other things, vaccinations and other preventive health behaviors are too low from a public health standpoint, meaning relative to virus exposure and the potential adverse consequences of infection in low-income and racial/ethnic minority populations. Furthermore, we hypothesize that small financial incentives and other low-cost behavioral nudges can be used to reduce disparities, increasing vaccination rates and other behaviors known to mitigate the spread of the virus.

1.5. * **Select which IRB you are requesting review from:**

- ( ) USC - Biomedical IRB
- (●) **USC - Social Behavioral IRB**
- ( ) CHLA - Institutional Review Board (CHLA)

Select **"USC – Biomedical"** if you are conducting biomedical research activities which fall under FDA jurisdiction (drugs, devices, etc.).

Select **"USC – Social Behavioral"** if you are conducting social behavioral research activities (community/field-based research such as survey and interview procedures, etc. that are not FDA regulated.).

NOTE: IRBAs and designated reviewers (Chairs, Vice Chairs, etc.) are currently assigned to review applications based on the type of research conducted. **Selecting the incorrect board may result in a delay of the review process**; and the application may be returned for the correct review board to be selected.

1.6. * **To the investigator's knowledge, does the Institution have financial and/or intellectual property interests in the sponsor or the products used in this project?**
An institutional conflict may occur when a financial interest of the institution has the potential to bias the outcome of research conducted by its employees or students or to create an unacceptable risk to human subjects.

○ Yes ● No

2. Study Personnel

2.1. Study Personnel and their roles:

	Last Name	First Name	Organization	Study Role	Certifications	Obtain Consent	Interact with Participants	Access Identifiable Data	Manage Audit Access to PHI/ePHI (CHLA Only)	COVID Attestation (USC Only)
View	Jacobson	Mireille	DAVIS SCHOOL OF GERONTOLOGY	Principal Investigator	HS GCP HIPAA	no	no	yes		✓
View	Chang	Tom	MARSHALL SCHOOL OF BUSINESS	Co-Investigator	HS GCP HIPAA	no	no	yes		✓

Who may be included as "key personnel" on an IRB submission?

Key Personnel are individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the protocol. Individuals who should be named on an IRB application are those who engage in the following:

a. conducting research through an interaction or intervention with human subjects for research purposes
b. participating in the consent process by leading it or contributing to it
c. directly recording or processing identifiable private information, including protected health information, related to those subjects for the purpose of conducting the research study

Who should NOT be listed as key personnel on an IRB submission:

Individuals paid by the institution to perform a service not part of or paid by the research project performing services that are typically performed for non-research purposes or fee for service:

- honest broker
- pharmacy employees dispensing investigations drugs
- hospital employees obtaining blood through a blood draw or collect urine and provide such specimens to investigators as a service
- radiology clinic employees performing chest x-rays and sending results to investigators as a service
- routine laboratory analyses of blood samples for investigators as a commercial service
- transcription of research study interviews as a commercial service
- not administering any study intervention being tested or evaluated under the protocol

2.2. Is the Principal Investigator a staff member, student, resident, fellow, postdoctoral scholar, other trainee, or visiting scholar/faculty member at USC/CHLA?

○ Yes ● No

2.5. Specify the group/organization who has reviewed this study for scientific merit:

○ Federal Agency (e.g. FDA, NIH, CDC, DOE, NSF, DOJ, etc.)

○ USC Norris Clinical Investigations Committee

○ Doctoral Dissertation Committee

● **Other**

○ None

2.5.1 Specify the other group/organization who has reviewed this study for scientific merit:
J-PAL North America

4. Funding Information

4.1. * **What existing or pending support will be used for this study?** (check all that apply)

- ☐ Cooperative Group (SWOG, COG, RTOG, etc.)
- ☐ CTSI
- ☐ Department of Defense (DOD) Funds
- ☐ Departmental/Institutional Funds
- ☑ **Federal Grant/Contract**
- ☑ **Foundation Grant/Contract**
- ☐ Industry
- ☐ Intramural/Internal Grant
- ☐ Residual Funds
- ☐ State or Local Grant/Contract
- ☐ Subcontract from another institution
- ☐ No Funding
- ☑ **Other**

Change of existing/addition of new funding sources and agencies will require an amendment.

4.1.1 Will you be submitting an Urgent Review request?
○ Yes ● **No**

4.1.2 Will any funds come from the National Institutes of Health (NIH)?
● **Yes** ○ No

4.2. **If the funding source has undergone separate review by the IRB (i.e., cooperative group grants, umbrella grants, multi-project/program grants, center grants), try to select it from the list using the 'Add' button. If the funding source is not displayed in the list, enter the information in question 4.4.**

Grant #	Principal Investigator	Grant Title

There are no items to display

4.2.1. **If the grants selected in question 4.2 fund multiple studies, please attach the specific pages of the grant that are relevant to THIS study.**

Name	Version	Modified
There are no items to display		

4.4. **Add the details of each source of funding for this study.**

	Sponsor	Principal Investigator	Type of Funding
View	National Institutes on Aging	Joe Doyle and David Laibson	Federal: Program Project/Multiple Project Grant *

4.5. **For those studies with a related award in the USC award system, Kuali Coeus, please use the "Find Now" button below to relate this study with the award(s):**

Related Awards (uncheck checkbox to remove):

PI First Name	PI Last Name	Institutional Proposal Number	USC Award Number	Project Title	Prime Sponsor Name	Sponsor Name	Project Start Date	Co Investigators
Mireille	Jacobson	00220372		COVID-19 and Preventive Health Behaviors in at-Risk Medicaid Populations		Abdul Latif Jameel Poverty Action Lab	2/1/2021	

5. Type of Study Review

5.1. **Select the type of review that you are requesting for this study:**

- ○ Full Committee Review
- ● **Expedited Review**
- ○ Exempt Review
- ○ Coded Specimens/Data

5.2. **Attach the protocol here. All studies require a fully developed protocol. If you have questions contact the IRB office to discuss.**

Name	Version	Modified
Amended Protocol - April 2021(0.05)	0.05	4/23/2021 3:26 PM

A grant proposal is not applicable, and should not be uploaded in lieu of a protocol (template is attached and will also be available on the OPRS website).

Protocol Template: Social-Behavioral

5.3. Attach the sponsor's template informed consent here.

Name	Version	Modified
There are no items to display		

5.4. If any study documents are password protected, enter the passwords here.

5.5. If there is a sponsor protocol number associated with this file, specify it here:

6. Study Locations

6.1. Identify the locations where the research activities described in this application will be performed (check all that apply):

- ☐ USC HSC - Health Sciences Associated Locations
- ☑ **USC UPC - University Park Associated Locations**
- ☐ CHLA
- ☑ **Other**

6.2. Will USC/CHLA serve as the reviewing IRB for the other sites (single IRB model)?

○ Yes ● **No**

6b. UPC Location(s)

This screen is required if you indicated UPC - University Park Associated Locations (Question 6.1.)

6b.1. UPC Locations (check all that apply and provide detail where indicated):

Location
☑ **Campus location (includes ISI and ICT)**
☐ Off-campus location

If campus location, please specify:
Davis School of Gerontology

6b.2. If off-campus location, please specify:

6d. Other Sites/Institutions

This screen is required if you indicated that USC/CHLA is the lead institution or is conducting the study at other sites (Question 6.2.1.1. or 6.2.2.).

6d.1. List ALL participating sites below:

Site Name	Address	Engagement
View Contra Costa Health Services	333 C Street, Martinez, CA 94553	

View	MIT/JPAL	400 Main Street E19-201 Cambridge, MA 02142 USA	
View	National Bureau of Economic Research (NBER)	1050 Massachusetts Ave, Cambridge, MA 02138	Engaged

9. Methods and Procedures - Selected Descriptors/Community Engaged Research

Note: The list of items below IS NOT an all-inclusive list of methods and procedures available to investigators. The list only includes items that will trigger additional questions specific to areas of research or are necessary for the review process.

9.1. This study will include: (check all that apply)

- [x] Data/specimens that will be collected for research purposes
- [x] Data/specimens that have been or will be collected for non-research purposes (e.g., clinical care, student records)

9.1.1. Will anyone in the study team (listed under Section 2.1) have direct in-person interaction with participants?

○ Yes ● **No**

9.2. Study Procedures: (check all that apply)

- [ ] Audio/Video Recordings or Photographs
- [ ] Behavioral Observations and/or Behavioral Experimentation
- [x] Behavioral Interventions
- [ ] Deception
- [ ] Interview/Focus Groups
- [ ] Population-based Field Study
- [ ] Psychophysiological Testing
- [x] Surveys/Questionnaires/Psychometric Testing
- [ ] Approved/Investigational Devices
- [ ] Biohazardous Substances (e.g. fresh tissue or tissue fluids, infectious agents, microorganisms, recombinant DNA, or shipment of biological material)
- [ ] Blood Collection
- [ ] Creation of a Data or Tissue Repository
- [ ] Magnetic Resonance Imaging (MRI)
- [ ] Stem Cells or Cell-Based Therapy

9.3. Is this a clinical trial? [The NIH defines a clinical trial as a prospective research study to evaluate the effects of one or more interventions on health-related biomedical or behavioral outcomes.]

● **Yes** ○ No

Clinical Trials must be registered on clinicaltrials.gov. All study personnel on studies meeting the NIH definition of clinical trials are required to satisfy the Good Clinical Practice (GCP) education requirement.

9.5. Will data from this study be subject to the NIH Genomic Data Sharing (GDS) policy?

○ Yes ● **No**

9.6. Does your study involve community-engaged research (community-engaged research addresses community needs and involves the community in research plan, conduct of study, etc)?

● **Yes** ○ No

9.6.1 How is the community involved? (select all that apply)

Community Advisory Board established for this study provides input

Study results are/will be disseminated to the community

9.7. Will data from this research be submitted to the US Food and Drug Administration or will data be held for inspection by the FDA?

○ Yes ● **No**

10. Characteristics of the Study Subject Population

10.1. What is the maximum number of subjects you plan to recruit for this site? (Integer values only)

10000

10.1.1. If this is a multi-site study, indicate the projected total subject accrual. (Integer values only)

10.1.2. If necessary, provide further explanation of accrual goals for all subject populations.

Baseline survey enrollment is targeted at 10,000.

10.3.1. If there are any age, ethnic, language, or gender-based exclusion criteria, please provide justification.

Ages 18 and over because they make health care decisions for themselves.

To analyze the issue of race concordance on vaccine take-up, we will focus on White, Black, and Latinos of any race. We will need to exclude racial minorities that are too small a share of the CCHP population to allow us to make inferences about race concordance. As a result, we exclude CCHP members identified as American Indian/Alaska Native and Hawaiian/Pacific Islanders as each group accounts for less than 1% of enrollees. We will also exclude Asians, a group that is very heterogenous generally and in Contra Costa specifically. When grouped together as a single "race," Asians account for about 15% of the CCHP population. However, that group is comprised of populations that are both linguistically and culturally quite distinct. In particular, about a third of the "Asian" group is Filipino, a third Vietnamese, 25% Mandarin-speaking Chinese, 20% Cantonese-speaking Chinese, 15% Punjabi-speaking Indian, 10% Laotian, 10% Korean, and so on. As such, we do not think these populations can credibly be treated as one group for the purposes of studying race concordance and yet each group is individually too small to consider alone.

13. Methods and Procedures - Collection of Data/Specimens

13.1. Does the study involve collection of data, records or specimens from deceased individuals?

○ Yes ● No

13.2. Attach a copy of the Data Collection forms you intend to use to access and record data for research purposes. Data Collection forms include a summary of the variables to be recorded from the original source.

Name	Version	Modified
Secondary data(0.01)	0.01	1/7/2021 3:19 PM

13.2.1. Will you be obtaining data from a clinical data warehouse (such as the CDW at Keck or LA County)?

● Yes ○ No

13.3. Describe the method of collection for the records/specimens and how the data/specimens will be analyzed.

13.3.a. Specify the number of records/specimens you expect to use: (*This is a deprecated field - only used for existing studies.*)

10000

13.4. Describe the method(s) by which subject records will be identified.

21. Methods and Procedures - Surveys/Questionnaires/Psychometric Testing

This screen is required if you indicated the use of Surveys, Questionnaires, or Psychometric Testing (Question 9.2.)

21.2. Attach copies of all measures/instruments that will be used for this study.

Name	Version	Modified
Baseline survey(0.01)	0.01	1/7/2021 3:24 PM

22. Special Subject Populations

22.1. Indicate any special subject populations you intend or expect to enroll in the research: (check all that apply)

- ☐ Healthy Volunteers
- ☐ Employees or Students
- ☐ Adults not Competent to Consent (or likely to lose the capacity to consent during the study)
- ☑ **Non-English Speaking Populations**
- ☐ Minors (subjects under 18 years of age)
- ☐ Pregnant Women / Human Fetuses

- [ ] Neonates (infants under 30 days old)
- [ ] Prisoners/Detainees
- [ ] Wards
- [ ] Military Personnel
- [ ] None of the above

22d. Special Subject Populations - Non-English Speaking Subjects

This screen is required if you indicated you will be recruiting non-English speaking subjects (Question 22.1.)

22d.1. Describe how you will communicate with non-English speaking participants for the purposes of obtaining informed consent, permission, and or assent. (check all that apply)

- [x] **Translated full consent, permission, and/or assent forms (incl. information sheets) with verbal interpretation by an authorized interpreter**
- [ ] Translated short forms with verbal interpretation by an authorized interpreter
- [ ] Other

22d.2. If the study will likely include subjects and families for whom Spanish is the primary language, the consent documents must be translated into Spanish. Select the method of translation.

- (●) **Investigator/Sponsor will provide the IRB with a translation of the approved consent form**
- ( ) Request that the IRB office translate (HSIRB Only)

Please be advised that a Certificate of Translation may be required if an outside translator is used.

22d.3. If the research will primarily include subjects who speak a language other than English or Spanish, the informed consent documents should be translated into that language. Indicate the languages and method of translation.

Language	Translation Method
There are no items to display	

23. Study Resources

23.1. Describe the time the investigators have available to conduct and complete the research and justify that it is sufficient. Please check-off the items that apply to this study.

- [ ] Employed interns, residents, fellows, or postdocs with dedicated time to conduct this research.
- [x] **Employed faculty and or staff with dedicated time to conduct this research.**
- [ ] Students with dedicated time as part of their training to conduct this research.

- [ ] Volunteers
- [ ] Other

23.2. Describe the staff and justify their qualifications. Please check-off the items that apply to this study.

- [ ] All biomedical investigators are privileged and credentialed to perform the study activities in the study locations.
- [x] **All study staff are trained and credentialed to perform the duties assigned to them.**
- [ ] All study staff have fulfilled the training mandated by their respective departments or institutions.
- [ ] Other

23.3. Describe the study facilities and justify they are adequate.
We will use the USC RedCAP system. We have funds to hire a research manager and a research assistant to help implement this work.

24. Subject Recruitment and Informed Consent

24.1. Recruitment Tools that will be used by the local site (check a box only if your site will control the use or distribution of the recruitment tool): (check ALL that apply)

- [ ] Brochures
- [ ] Clinical Data Warehouse
- [x] **Email/Electronic Mailing Lists**
- [ ] Flyers
- [ ] Letters
- [ ] Newspaper/Magazine Advertisements
- [ ] Radio/Television Announcements
- [ ] Subject or Participant Pools
- [ ] Telephone Scripts
- [ ] Verbal (Personal Solicitation)
- [ ] Websites / Social Media Outlets
- [x] **Other**

☐ None of the above

24.1.1. Please specify:
Text

24.1.2. Describe how you will be obtaining contact information:
CCHS will provide a list of eligible patients

24.2. Attach copies of all recruitment tools that will be used by the local site. *(Do not attach any advertising or recruitment materials that will not be used at the local site or under control of the local site.)*

Name	Version	Modified
Recruitment email text(0.02)	0.02	2/26/2021 4:38 PM

24.3. Informed Consent and Waivers:

**** Please note that child assent and parental permission will be addressed on subsequent pages. Do not complete the following consent questions if adults will not be participating in the study. ****

Check the type(s) of consent or waiver of consent planned for this study: (check ALL that apply)

- ☑ **Written/signed consent (participants will sign an informed consent document)**
- ☐ Alteration of the elements of consent (participants will sign a consent document, but one or more of the basic required elements of consent will be altered or waived)
- ☐ Waiver of signed informed consent (informed consent document without the signature sections will be provided)
- ☐ Waiver of consent (participants will not be asked to sign or be given a consent document)

24.7. Attach copies of the informed consent documents(s), information sheets, and any statements of new information/findings or consent addenda (as applicable) that will be used in this study. This set should also contain any assent or parental permission documents that will be used.

Name	Version	Modified
Consent_4-27-2021(0.08)	0.08	4/27/2021 8:34 PM
HIPAA Authorization (approved by Compliance)(0.03)	0.03	4/27/2021 8:35 PM

Click here to obtain an IRB Informed Consent Template and instructions for preparing the consent form.
Consent forms submitted to the IRB should comply with these instructions.

Personnel from section 2.1 obtaining consent/permission/assent:
- none -
If the above list is incomplete or incorrect, please navigate to item 2.1 and make your changes there.

24.8. Describe the circumstances and location of the process of informed consent: (check ALL that apply)

- ☐ In a private area

- [ ] In a waiting room, open ward, group, or public setting
- [x] **Online, over the telephone, by mail, or via fax**
- [ ] Other

** NOTE: When participants sign the informed consent electronically, a copy of the informed consent document must be provided to them.

24.9. Describe how you will assess the individual's comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating. (check ALL that apply)

- [x] **An assessment tool will be used. (attach a copy of the tool below)**
- [ ] This will be verbally assessed. Individuals will be asked to answer the following questions (as applicable): (1) What are you being asked to do? (2) What question is this study trying to answer? (3) What are the potential risks of participating in this study? (4) How often will you need to come in for study visits? (5) What is the difference between participating in this study and your standard medical care? (6) What should you do if you decide to withdraw from the study?
- [ ] Other (specify below)

24.9.1. Assessment Tool:

Name	Version	Modified
Quiz(0.02)	0.02	1/7/2021 3:06 PM

24.10. Describe all measures that will be taken during the recruitment and consent process to ensure that individuals have adequate time to consider participation and to safeguard against potential coercion and undue influence: (check ALL that apply)

- [x] **The informed consent process will begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant in understanding the reasons why one might or might not want to participate in the research**
- [x] **They will not be forced, threatened or coerced in any way to participate in this research, and no undue influence or other form of constraint will be used to recruit individuals to participate in this research or to retain currently enrolled subjects. (Note: "Coercion" is the use or threat of the use of force to gain compliance. "Undue influence" is when an individual who is in a position of authority (e.g., physician, teacher, employer) exerts inappropriate or excessive manipulation to gain power and compliance over a vulnerable individual (potential research subject). "Constraint" means force, obligation, or pressure.)**
- [x] **They will not be punished or denied something which they would normally receive (e.g., threatening to withdraw health services to which an individual would otherwise be entitled) if they choose not to participate in this research or choose to withdraw early from participation.**
- [x] **They will be given an adequate amount of time to consider participation in the study relative to the initiation of study procedures.**
- [x] **The information presented to individuals during recruitment and consent will reflect that provided in the informed consent document/informed consent script.**
- [x] **The recruitment and consent process will not promise them a certainty of cure or benefit beyond what is outlined in the informed consent document/informed consent script.**
- [x] **The recruitment and consent process will take place in an area in which it is possible to maintain privacy and confidentiality.**
- [ ] They will be given the opportunity to take the informed consent document home in order to discuss participation with their family, friends and/or others before making a definitive decision.
- [ ] They will receive payment for their participation, but the amount of payment will be commensurate with their participation (not an inducement for participation), and receipt of the payment will not be contingent upon the individual's completion of the study. (Note: The specific method, schedule, and amount of payment must be outlined in the payment section of the

application.)

☐ Other (explain below)

25. Financial Obligation and Compensation

25.1. Financial Obligation: Choose the response that best describes the cost to participants.

○ All costs are covered by the sponsor or funder.

○ Research costs are paid by the sponsor or funding agency; routine health care costs are the responsibility of the participants and/or their healthcare plans.

○ All costs are the responsibility of the participants and/or their healthcare plans.

○ Drug trials sponsored by the National Cancer Institute or other national institutes.

● **There are no costs related to participation.**

○ Other

25.2. Payment for Participation: Describe how much, if any, financial or other form of compensation will be provided to the subject/family. Describe the requisite conditions that must be fulfilled to receive full or partial compensation. Describe the proposed method of timing and disbursement. If children are involved, please specifically address how the compensation will be distributed to children.
Individuals who consent to the study and complete the baseline survey will receive a $5 gift card. They will also be eligible for a raffle. We will raffle off 20 gift cards at $250 per card.

We also have financial incentives for vaccine take-up. Specifically, we will randomly vary incentives for vaccination at $10 and $50. These incentive values are in line with the prior literature. For example, Bronchetti, Huffman, and Magenheim (2015) paid college students $30 for flu vaccinations in 2012. In addition, the $50 incentive is in-line with 2 hours of time at the minimum wage plus transportation costs. As noted in our protocol, many behavioral economic studies that have been approved by IRBs at peer institutions vary incentive amounts for the same activitiy.

This design will enable CCHS to understand the potential costs and benefits of a financial assistance program to increase vaccinations more generally, e.g., influenza vaccination, something they are considering for vaccinations generally, i.e., not only COVID-19 vaccination. Without varying these incentives, we cannot provide CCHS with a good estimate of how to cost-effectively design such a program in the future. While we understand concerns about equity, deception, which has been suggested by the IRB as a way to equalize payments ex-post, is not viewed as acceptable practice in our field (economics). In addition, we think it would be potentially harmful to use deception to study infectious disease in low-income disparity populations.

26. Participant Privacy and Data Confidentiality

26.1. Privacy Protections: Privacy is a participant's ability to control how other people see, touch, or obtain information about his/her self. Violations of privacy can involve circumstances such as being photographed or videotaped without consent, being asked personal questions in a public setting, being seen without clothing, being observed while conducting personal behavior, or disclosing information about abortions, HIV status, or illegal drug use.

Select the provisions to protect the privacy of the individual during screening, consenting, and conduct of the research: (check ALL that apply)

☐ Research procedures will be conducted in person in a private setting.

- [ ] Data will be captured and reviewed in a private setting.
- [ ] Only authorized research study personnel will be present during research related activities.
- [x] **The collection of information about participants is limited to the amount necessary to achieve aims of the research.**
- [ ] Participants will not be approached in a setting or location that may constitute an invasion of privacy or could potentially stigmatize them.
- [ ] Other (specify below)

26.2. **Confidentiality Precautions:** Confidentiality is an extension of the concept of privacy; it refers to the participant's understanding of, and agreement to, the ways identifiable information will be collected, stored, and shared. Identifiable information can be printed information, electronic information, or visual information such as photographs.

How will the research data/specimens be labeled? (check ALL that apply)

- [ ] Data and/or specimens will be directly labeled with personal identifying information. (Identifiable)
- [x] **Data and/or specimens will be labeled with a code that the research team can link to personal identifying information. (Coded)**
- [ ] Data and/or specimens will not be labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information. (Anonymous)
- [ ] Other (explain below)

26.3. **Study data/specimen will be stored:**

- [ ] Physically
- [x] **Electronically**

Which devices will have study data:

- [ ] Local computers/laptops
- [ ] Removable drives (USB, external drives)
- [ ] Local Server(s)
- [x] **External Servers (including cloud based services)**

Which company/organization will be providing the service?
Box.com

Note: Please ensure that the third party's technical infrastructure meets or exceeds the minimum standards set out by ITS.

Please confirm that, at a minimum, the following measures will be taken and enforced:

- [ ] Information or specimens maintained physically will be stored with appropriate physical safeguards, such as in locked cabinets and/or in restricted areas limited to authorized study personnel

- [x] **Electronic data will be stored with appropriate electronic safeguards, such as unique usernames/passwords, and limited to authorized study personnel. Dual factor authentication will be used, if feasible.**
- [ ] Copying and use of study related materials will be restricted
- [x] **Security software (firewall, antivirus, anti-intrusion) will be installed and regularly updated in all servers, workstations, laptops, and other devices used in the study**
- [x] **All computers with access to study data will be scanned regularly (for viruses and spyware, etc.) and problems will be resolved**
- [ ] Data stored on a removable drive will be encrypted and have proper access controls
- [x] **Data transfer will be encrypted**

26.4. Will identified data and/or specimens be sent outside the institution to a third party (such as a study sponsor, federal agency, or another institution)?

○ Yes ● **No**

26.5. What will happen to the research data and/or specimens at the conclusion of the study? (check ALL that apply)

- [x] **Direct identifiers and/or the key to the codes will be destroyed upon completion of the research (all data/specimens will be stripped of identifying information and/or the key to codes destroyed, paper documents shredded, electronic files purged, electronic media securely erased)**
- [ ] Retained for study record keeping purposes per institutional policy
- [ ] Retained by the investigator for future research use
- [ ] Retained for future research use (submit data or tissue to an existing repository/bank)
- [ ] Restricted use data will be destroyed or returned to the source
- [ ] No direct or indirect identifiers are being collected. The anonymous data and/or specimens will be retained at the discretion of the investigator
- [ ] This research is a clinical trial conducted under FDA regulations. Direct identifiers and/or the key to the codes will be destroyed as directed by the sponsor (IND/IDE holder) in accordance with FDA regulations
- [ ] The NIH requires that the records be retained for three years following the completion of the study
- [ ] Other (specify below)

26.6. Do you have, or plan to apply for, a Certificate of Confidentiality for this study?

○ Yes ● **No**

NOTE: NIH-funded research in which identifiable, sensitive information is used, including research that:

- **Meets the definition of human subjects' research, including exempt research in which subjects can be identified**
- **Is collecting or using human bio specimens that are identifiable or that have a risk of being identifiable**
- **Involves the generation of individual level human genomic data**
- **Involves any other information that might identify a person**

is automatically protected by a certificate of confidentiality from the NIH.

27. Risk/Benefit Assessment - Risks

27.1. **Risks, Discomforts and Potential Harms: Describe the risks associated with each research intervention. Include consideration of physical, psychological, social, and other factors.** (check all that apply)

- [ ] Discrimination based on genetic findings.
- [ ] Some people may find it upsetting to learn that they have certain mutations or errors in genes that could lead to future health problems for themselves or their children.
- [x] **Some of the questions may make the participant feel uneasy or embarrassed.**
- [x] **There is a small risk that people who are not connected with this study will learn a participant's identity or their personal information.**
- [ ] The participants are providing highly sensitive, personal information in this study. If people not connected with the study learn this information, they could have problems getting a new job, keeping their current job, finding housing, or getting insurance (health, disability, or life insurance). In highly unlikely situations, they could be charged with a crime.
- [ ] Biomedical risks, including drug, device, biologics, radiation, surgery or other research procedures (please specify).
- [ ] The research includes the risk or disclosure that a participant may engage in self-harm or attempt suicide.
- [ ] Venipuncture risks including: mild discomfort (or pain), bruising and swelling around the puncture site, dizziness or fainting, or infection (rare).
- [ ] Other (specify below)

27.2. **Describe the precautions that will be taken to minimize risks/harms.** (check all that apply)

- [x] **We will use our best efforts to keep the findings in this study as confidential as possible.**
- [x] **Subjects can choose to skip or stop answering any questions that make them uncomfortable.**
- [x] **Data will be coded and identity stored separate from data.**
- [ ] Data will be collected anonymously.
- [ ] Biomedical precautions, including precautions relating to drugs, devices, biologics, radiation, surgery or other research procedures (please specify).
- [ ] Venipuncture by individuals certified and privileged to perform the procedure.
- [ ] Other (specify below)

28. Risk/Benefit Analysis - Potential Benefits and Alternatives

28.1. **Describe any potential for direct benefits to participants in the study:** (check all that apply)

- [x] **There are no direct benefits to research participants**
- [ ] Improvement in some or all of participants' symptoms

- ☐ Improvement in some or all of participants' survival or longevity
- ☐ Information gained from testing or monitoring procedures
- ☐ Provision of drug or device
- ☐ Reduced side effects
- ☐ Other (explain below)

28.2. Describe potential benefits to society, if any. (check all that apply)

- ☐ The advancement of knowledge
- ☐ A new treatment or therapy for the condition under study
- ☐ None
- ☑ **Other (explain below)**

28.2.1. Describe other potential benefits to society:
If we can increase vaccine take-up, we increase the likelihood of herd immunity. We will also generate broader evidence on how to increase vaccine take-up generally.

28.3. What are the alternatives to participation? (check all that apply)

- ☑ **Not participating**
- ☐ Continue current medical care for their condition
- ☐ Participation in other research studies
- ☐ Palliative care
- ☐ No treatment or therapy
- ☐ Participate in other subject pool activities
- ☐ Other (specify below)

28.4. Risks in relation to benefits:

- ☐ The potential benefits to the research participants justify exposure of the participants to the risks.
- ☑ **The potential benefits to humanity justify exposure of the participants to the risks.**
- ☐ Other (specify below)

35. Is the HIPAA Privacy Rule Applicable?

35.1. Do you intend to access, review, collect, use, or disclose Protected Health Information (PHI/ePHI) which includes either patient and/or participant data, in your research? Answer yes if you intend to do any of the following:

- Look at medical records (paper or electronic) to identify potential research participants
- Look at clinic logs to identify potential research participants
- Record demographic information obtained from medical records (paper or electronic)
- Record health information obtained from medical records (paper or electronic)
- Obtain information from laboratory reports, pathology reports, radiology reports or images, or other reports from medical or mental health testing and treatment
- Obtain information from medical billing records
- Record or use medical record numbers or other information that could be used to identify an individual (review the list of HIPAA identifiers below)
    - Name/Initials
    - Street address, city*, county*, precinct*, zip code*, or equivalent geocodes*
    - All elements of dates (except year) directly related to an individual (date of birth, admission date, discharge date, date of death)*
    - Elements of date, including year, for persons 90 or older
    - Telephone number
    - Fax number
    - Electronic mail address
    - Social Security Number
    - Medical record number
    - Health plan identification number
    - Account number
    - Certificate/license number
    - Vehicle identifiers and serial numbers, including license plate number
    - Device identifiers and serial number
    - Web addresses (URLs); Internet IP addresses
    - Biometric identifiers, including finger and voice print
    - Full face photographic images and any comparable images
    - Any other unique identifying number, characteristic, or code*

● **Yes** ○ No

35.2. **Do you intend to record data that contains any of the 18 elements defined by HIPAA as identifiers (listed above), in your research?**

● **Yes** ○ No

35.3. **Are you going to record only the personal identifiers marked with an asterisk (*)? If so, you may be able to obtain or use such health information from a healthcare provider for research purposes without an authorization. Under the HIPAA Privacy Rule, this data constitutes a limited data set. if you are creating or obtaining a limited data set, you must complete a Data Use Agreement. Attach a copy of the signed Data Use Agreement below.**

Name	Version	Modified
There are no items to display		

35.4. **Will you be recording HIV data?**

○ Yes ● **No**

35.5. **Will you be collecting or accessing mental health records from a mental health practitioner?**

○ Yes ● **No**

35.6. **Will you be collecting or accessing substance abuse treatment records?**

○ Yes ● **No**

USC Template Data Use Agreement

** If your Data Use Agreement does not use USC's template form, please contact USC's Office of Compliance at complian@usc.edu or 213-740-8258 to submit the Data Use Agreement for further review and approval.

36. HIPAA Analysis

This screen is only required if you indicated HIPAA is applicable by answering "yes" to Question 35.1.

36.1. If you are using or accessing protected health information in order to identify potential participants, indicate if you will be applying for a Partial Waiver of HIPAA Authorization for the purposes of screening and recruiting.

- (●) **Partial Waiver of HIPAA Authorization for screening, recruiting, and identifying participants**
- ( ) None of the Above

36.2. If you are using or accessing protected health information to conduct the research, please select whether you will be obtaining authorization from the participant or requesting a Full Waiver of HIPAA Authorization.

- (●) **Obtaining HIPAA authorization from participant**
- ( ) Full Waiver of HIPAA Authorization
- ( ) Both

Click here **to download the "Instructions for Completing HIPAA Research Authorization Form" and the HIPAA research authorization forms approved by the USC Office of Compliance (scroll down to "Research (300))".**

36.2.1. Assurance:

- (●) **I agree to use the current HIPAA research authorization forms and make only those changes described in the "Instructions for Completing HIPAA Authorization Form."**
- ( ) I modified the HIPAA research authorization form and received approval from the USC Office of Compliance to use the modified form.

38. Partial Waiver of HIPAA Authorization

This screen is required only if HIPAA is applicable and you indicated you are requesting a Partial Waiver of HIPAA Authorization (Question 36.1.)

If you are applying for a partial waiver of authorization for the purposes of screening, recruitment, and subject identification, provide justification per 45 CFR 164.

38.1. How will you protect PHI/ePHI (Protected Health Information) from improper use and disclosure? (check all that apply)

- [ ] PHI/ePHI will be used only for the purposes of assessing eligibility and identifying potential participants.
- [x] **All source and research documents containing PHI/ePHI will be stored and maintained in a locked/password protected area accessible only to study staff.**
- [x] **Study data will be coded or de-identified prior to being sent outside the study team.**
- [ ] Other

38.2. How will you destroy identifiers at the earliest opportunity consistent with the conduct of the research? (check all that apply)

- [x] **No identifiers or links to identifiers will be recorded during the data collection process.**
- [x] **Direct or Coded Identifiers will be maintained only until the study is completed. After that, the identifiers will be shredded and electronic records purged.**

- [x] The link between study participants and study ID numbers will be destroyed (shredded/purged) when study activities are complete.
- [ ] Other

38.3. By checking the "I Agree" box you are providing assurance that PHI/ePHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI/ePHI is permitted by the Privacy Rule.

- [x] I Agree

38.4. The research could not practicably be conducted without the requested waiver or alteration because: (check all that apply)

- [x] PHI/ePHI is required to identify potential participants who meet the eligibility criteria.
- [ ] Other

38.5. The research could not practicably be conducted without access to and use of the PHI/ePHI because: (check all that apply)

- [x] PHI/ePHI is required to identify potential participants who meet the eligibility criteria.
- [x] During the recruitment process, PHI/ePHI is needed in order to contact potential participants.
- [ ] Other

38.6. By checking the "I Agree" box you are providing assurance that PHI/ePHI requested will be the minimum amount necessary to conduct the research or meet the research objectives.

- [x] I Agree

39. Conflict of Interest Information

39.1. Indicate the Study team member(s) that have a potential conflict of interest. For each person to be designated, click on his/her name and select the disclosure(s) that should be associated with this study.

Study Staff	Role	COI Annual Disclosure Status	Conflicts
Mireille Jacobson	Principal Investigator	Current: due on 7/31/2021	No conflicts identified
Tom Chang	Co-Investigator	Current: due on 7/31/2021	No conflicts identified

40. Additional Supporting Documents

40.1. Attach any other documents that have not been specifically requested in previous questions, but are needed for IRB review.

Name	Version	Modified
MIT JPAL - SMART IRB Determination(0.01)	0.01	3/22/2021 11:54 AM
NBER IAA(0.01)	0.01	4/28/2021 8:50 AM

40.2. If there is any additional information that you wish to communicate about the study include it below. Please note, this section should not be used instead of the standard application items.
As mentioned elsewhere, many behavioral economics studies vary incentives for the same behavior. The amended protocol lists several recent studies that are relevant. Here we list a few others for the IRB's consideration:

1) Volpp, K.G., Loewenstein, G., Troxel, A.B. et al. A test of financial incentives to improve warfarin adherence. BMC Health Serv Res 8, 272 (2008). https://doi.org/10.1186/1472-6963-8-272.
https://bmchealthservres.biomedcentral.com/articles/10.1186/1472-6963-8-272

Study participants were randomized to be entered into a daily lottery of $10 or $100 for warfarin adherence.

This study was approved by the IRB at University of Pennsylvania.

2) Alicea Lieberman, Ayelet Gneezy, Emily Berry, Stacie Miller, Mark Koch, Chul Ahn, Bijal A. Balasubramanian, Keith E. Argenbright and Samir Gupta, Financial Incentives to Promote Colorectal Cancer Screening: A Longitudinal Randomized Control Trial Cancer Epidemiol Biomarkers Prev November 1 2019 (28) (11) 1902-1908; DOI: 10.1158/1055-9965.EPI-19-0039

Patients were randomized to receive outreach alone or outreach and either incentives of $5 or $10 for completion of a fecal immunochemical test (FIT).

This study was approved by the IRB at Texas Southwestern Medical Center

3) Beshears, John, Hae Nim Lee, Katherine L. Milkman, Robert Mislavsky, and Jessica Wisdom, Creating Exercise Habits Using Incentives: The Tradeoff between Flexibility and Routinization, Management Science
https://pubsonline.informs.org/doi/10.1287/mnsc.2020.3706

This study tried to increase exercise. Participants were randomly assigned to a control that received daily reminders, daily reminders and either $3 or $7 for each gym visit in a 4-week period or daily reminders and either $3 or $7 for each gym visit within a 2-hour pre-selected window in a 4-week period.

This study was approved by the IRBs at Harvard, the National Bureau of Economic Research and the University of Pennsylvania.

41. Feasibility Information for Scientific Review

This page is required when the research has not yet undergone scientific review.

41.1. What is the expected duration of the accrual period?
1 month for baseline study recruitment

41.2. Describe any competing studies at USC (i.e. studies with similar inclusion/exclusion criteria and similar recruitment timeframes). Include investigator names and study titles, if known.
None that I am aware of.

41.3. Describe the study team's expertise and experience relevant to this study.
The study investigators have been collaborating with CCHS on an internally-funded project, ﷺBehavioral Response to COVID-19 Testing,ﷺ since May 2020. In that work, we are fielding an initial and follow-up survey to Medicaid managed care enrollees coming to CCHS for clinician-ordered blood lab work as well as to individuals coming to county public health diagnostic testing sites. A subset of the blood lab sample is randomly offered free COVID-19 antibody testing, with the goal of understanding how antibody testing affects behaviors. We ceased recruiting at the end of the week of September 14. Since July, about 2,100 respondents have filled out an initial survey and nearly 1,800 have been invited via text and/or email to a follow-up survey. At present, we have just over 1330 follow-up surveys of these individuals via email or text to the follow-up surveys completed. Despite offering only a $5 incentive for survey completion and the chance to win a $500 gift card, the follow-up survey response rate has remained at about 74% for the past month. That work effectively serves as a pilot for this

project.

41.4. Describe the resources required to conduct this study and plans for accessing them. Examples of resources include equipment, facilities, and materials.
We will use the USC RedCAP system. We have funds to hire a research manager and a research assistant to help implement this work.

42. Clinical Data Warehouse

This screen is required if you indicated the use of a clinical data warehouse in 13.3.1 or 24.1

42.1. Which Clinical Data Warehouse(s) will you be using?

- [ ] Keck Medicine of USC
- [ ] LA County/DHS
- [x] **Other**

42.1.1. Please Specify the other clinical data warehouse(s) you will be using:
Contra Costa Health Services Data Warehouse

42.2. Which of the following HIPAA Identifiers will you be recording?

- [x] **Name**
- [x] **Address**
- [ ] All elements (except years) of dates related to an individual
- [x] **Telephone numbers**
- [ ] Fax number
- [x] **Email address**
- [ ] Social Security Number
- [x] **Medical record number**
- [ ] Web Universal Resource Locators (URLs)
- [ ] Device identifiers and serial numbers
- [ ] Vehicle identifiers and serial numbers, including license plate numbers
- [ ] Internet Protocol (IP) addresses
- [ ] Biometric identifiers, including finger and voice prints
- [ ] Health plan beneficiary numbers

- ☐ Full-face photographs and any comparable images
- ☐ Account numbers
- ☐ Any other unique identifying number, characteristic, or code
- ☐ Certificate/license numbers
- ☐ None of the 18 HIPAA identifiers will be recorded or stored as part of this study.

42.3. Do you intend to contact people identified from the data obtained from the clinical data warehouse?
● Yes ○ No

42.3.1. Please indicate how you will be contacting them:
E-mail or text.

99. Instructions for Submission

You have reached the end of the application. When you are sure of the content, the following steps may be taken to submit your application for review.

1. Click the **"Finish"** button on the top or bottom application navigator bar to return to the workspace.
2. Use the **Hide/Show Errors** above to determine that all sections of the application are filled out correctly.
3. Use the **"Send Study Ready Notification"** activity to send an email to the Principal Investigator and Co-Investigators with instructions for reviewing and submitting the application.
4. **All listed Co-Investigators (indicated in item 2.1.) must use the "Agree to Participate" activity and answer yes.**
5. Once all the Co-Investigators have agreed to participate, the **Principal Investigator** (indicated in item 2.1.) can submit the application by using the **"Submit Application to ____"**, where ____ indicates the IRB you are submitting to.
6. The PI will have to check the PI endorsement box. The PI will also have to check the student endorsement box if it is applicable.
7. The application is submitted. The state indicator in the top left of the workspace will no longer display Pre Submission.
8. The PI and Study Contact Person will receive an email confirming the application has been submitted.

4.4. Funding Source

Please enter the fields below and click 'OK' when done.

4.4.1. * **Name of Sponsor:**
National Institutes on Aging

4.4.2. * **Named Principal Investigator:**
Joe Doyle and David Laibson

4.4.3. **Institution awarded the grant-award:**
National Bureau of Economic Research

4.4.4. **Grant-award number provided by the Sponsor:**
5P30AG034532-12

4.4.5. **Title of the Funding Project, if applicable:**

4.4.6. * **Type of Funding:**
Federal: Program Project/Multiple Project Grant *

4.4.7. Attach a copy of the proposal/contract/grant with the project budget. Copies of the documents submitted to the funding agency, including the budget detail, should be submitted. (salary information need not be displayed or included.)

Name	Version	Modified
There are no items to display		

6d.1 Other Site

Please complete the form below and click 'OK' when done.

6d.1.1. * **Site Name:**
Contra Costa Health Services

6d.1.2. * **Address:**
333 C Street, Martinez, CA 94553

☐ **International (Check here if [site] is not in the United States)**

6d.1.3. * **Briefly describe the activities that will occur at [site]:**
We are recruiting from members of CCHS,.

6d.1.4. Determining Engagement:

Will [site] personnel conduct any of the following activities?

* **6d.1.4.1. Recruitment and Consent:**

Inform potential participants of the availability of the research, provide study contact information, or seek permission for investigators to contact the potential participants?
● **Yes** ○ No

Obtain informed consent from the research participants?
○ Yes ● **No**

* **6d.1.4.2. Participant Data and Information:**

Release to the study investigators data or information about the research participants that have been collected for non-research purposes?
● **Yes** ○ No

Obtain identifiable data or information about the research participants solely for the purposes of the research project?
○ Yes ● **No**

* **6d.1.4.3. Participant Contact and Intervention:**

Interact with the research participants for routine care, follow up or commercial services?
● **Yes** ○ No

Interact or intervene with research participants for research purposes (including performing procedures or manipulating the environment)?
○ Yes ● **No**

* 6d.1.5. **Will [site] receive any direct federal support for this research?**
◯ Yes ● **No**

Your answers indicate that [site] is engaged in the research. You must answer the following:

6d.1.8. **Under which IRB Authorization Agreement will [site] rely on the USC/CHLA IRB to review this study?**
◯ SMART IRB
● **Other**

Provide the name of the agreement:
IRB Authorization Agreement

Upload the agreement, if available:

6d.1.9. **Please attach a letter from [site] acknowledging that the study may be conducted there.**

Name	Version	Modified
CCHS IRB memo.pdf(0.01)	0.01	3/15/2021 6:20 PM
LOS Shah J-PAL.pdf(0.01)	0.01	2/19/2021 5:09 PM

6d.1.9. **Will any of the personnel at [site] carry out research activities such as obtaining consent or conducting study procedures?** (Deprecated Field - used to be 6c.1.3. - only used for old studies) ◯ Yes ◯ No

6d.1.10. **If yes, indicate under which category(ies) [site] is engaged** (see guidance) **and attach a copy of the IRB approval from [site] below.** (Deprecated Field - old 6c.1.4. - only used for old studies)

	Short Description
☐	(1) Institutions that receive an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research.
☐	(2) Institutions whose employees or agents intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures.
☐	(3) Institutions whose employees or agents intervene for research purposes with any human subject of the research by manipulating the environment.
☐	(4) Institutions whose employees or agents interact for research purposes with any human subject of the research.
☐	(5) Institutions whose employees or agents obtain the informed consent of human subjects for the research.
☐	(6) Institutions whose employees or agents obtain for research purposes identifiable private information or identifiable biological specimens from any source for the research.

6d.1 Other Site

Please complete the form below and click 'OK' when done.

6d.1.1. * **Site Name:**
MIT/JPAL

6d.1.2. * **Address:**
400 Main Street E19-201 Cambridge, MA 02142 USA

☐ International (Check here if [site] is not in the United States)

6d.1.3. * Briefly describe the activities that will occur at [site]:
MIT/J-PAL is the funder. J-PAL gets their funding from foundations as well as donations. As such, this is technically a sub-award and so they need IRB approval.

6d.1.4. Determining Engagement:

Will [site] personnel conduct any of the following activities?

* 6d.1.4.1. Recruitment and Consent:

Inform potential participants of the availability of the research, provide study contact information, or seek permission for investigators to contact the potential participants?
○ Yes ● No

Obtain informed consent from the research participants?
○ Yes ● No

* 6d.1.4.2. Participant Data and Information:

Release to the study investigators data or information about the research participants that have been collected for non-research purposes?
○ Yes ● No

Obtain identifiable data or information about the research participants solely for the purposes of the research project?
○ Yes ● No

* 6d.1.4.3. Participant Contact and Intervention:

Interact with the research participants for routine care, follow up or commercial services?
○ Yes ● No

Interact or intervene with research participants for research purposes (including performing procedures or manipulating the environment)?
○ Yes ○ No

* 6d.1.5. Will [site] receive any direct federal support for this research?
○ Yes ● No

Your answers indicate that [site] is engaged in the research. You must answer the following:

6d.1.8. Under which IRB Authorization Agreement will [site] rely on the USC/CHLA IRB to review this study?
● SMART IRB
○ Other

6d.1.9. Will any of the personnel at [site] carry out research activities such as obtaining consent or conducting study

procedures? (Deprecated Field - used to be 6c.1.3. - only used for old studies) ◯ Yes ◯ No

6d.1.10. If yes, indicate under which category(ies) [site] is engaged (see guidance) and attach a copy of the IRB approval from [site] below. (Deprecated Field - old 6c.1.4. - only used for old studies)

	Short Description
☐	(1) Institutions that receive an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research.
☐	(2) Institutions whose employees or agents intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures.
☐	(3) Institutions whose employees or agents intervene for research purposes with any human subject of the research by manipulating the environment.
☐	(4) Institutions whose employees or agents interact for research purposes with any human subject of the research.
☐	(5) Institutions whose employees or agents obtain the informed consent of human subjects for the research.
☐	(6) Institutions whose employees or agents obtain for research purposes identifiable private information or identifiable biological specimens from any source for the research.

6d.1 Other Site

Please complete the form below and click 'OK' when done.

6d.1.1. * **Site Name:**
National Bureau of Economic Research (NBER)

6d.1.2. * **Address:**
1050 Massachusetts Ave, Cambridge, MA 02138

☐ **International (Check here if [site] is not in the United States)**

6d.1.3. * **Briefly describe the activities that will occur at [site]:**
The NBER is a funder through the NBER Roybal Center for Behavior Change in Health. No research will be performed there but they are requesting an IRB agreement.

6d.1.4. Determining Engagement:

Will [site] personnel conduct any of the following activities?

* **6d.1.4.1. Recruitment and Consent:**

Inform potential participants of the availability of the research, provide study contact information, or seek permission for investigators to contact the potential participants?
◯ Yes ● **No**

Obtain informed consent from the research participants?
◯ Yes ● **No**

* **6d.1.4.2. Participant Data and Information:**

Release to the study investigators data or information about the research participants that have been collected for non-research purposes?
◯ Yes ● **No**

Obtain identifiable data or information about the research participants solely for the purposes of the research project?

◯ Yes ● **No**

* **6d.1.4.3. Participant Contact and Intervention:**

Interact with the research participants for routine care, follow up or commercial services?
◯ Yes ● **No**

Interact or intervene with research participants for research purposes (including performing procedures or manipulating the environment)?
◯ Yes ● **No**

* **6d.1.5. Will [site] receive any direct federal support for this research?**
● **Yes** ◯ No

Your answers indicate that [site] is engaged in the research. You must answer the following:

6d.1.6. Does [site] have an IRB?
● **Yes** ◯ No

6d.1.6.1. Will [site]'s IRB review this research?
◯ Yes ● **No**

* **6d.1.6.2. Attach the IRB approval or, if [site] has elected to have USC/CHLA be the IRB of record, attach the IRB authorization agreement.**
IAA - Jacobson Vaccination NBER Fully Executed.pdf(0.02)

6d.1.7. Please provide the following assurance:

☑ **All unexpected problems, protocol modifications, and interim results will be communicated to [site] and regulatory agencies (as applicable).**

6d.1.8. Under which IRB Authorization Agreement will [site] rely on the USC/CHLA IRB to review this study?
◯ SMART IRB
◯ Other

6d.1.9. Will any of the personnel at [site] carry out research activities such as obtaining consent or conducting study procedures? (Deprecated Field - used to be 6c.1.3. - only used for old studies) ◯ Yes ◯ No

6d.1.10. If yes, indicate under which category(ies) [site] is engaged (see guidance) **and attach a copy of the IRB approval from [site] below.** (Deprecated Field - old 6c.1.4. - only used for old studies)

	Short Description
☐	(1) Institutions that receive an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research.
☐	(2) Institutions whose employees or agents intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures.
☐	(3) Institutions whose employees or agents intervene for research purposes with any human subject of the research by manipulating the environment.

☐ (4) Institutions whose employees or agents interact for research purposes with any human subject of the research.

☐ (5) Institutions whose employees or agents obtain the informed consent of human subjects for the research.

☐ (6) Institutions whose employees or agents obtain for research purposes identifiable private information or identifiable biological specimens from any source for the research.

Amended Protocol – April 2021 (0.05)

- Participants: Adult patients impaneled at Contra Costa Regional Medical Center (CCRMC) who are eligible for COVID-19 vaccination based on county and CCRMC determination.
    - Adults ages 18+, eligible for vaccination (as determined by the county)
    - Self-identified as African American/Black, White or Latino (irrespective of race).
    - Children are not included as they do not make their own health care decisions. We are interested in how adults make decisions about their own COVID-19 vaccination and other preventive health behaviors.
    - We are not explicitly studying a protected population. Prisoners are not impaneled at CCRMC. Pregnant women, to the extent they are not excluded in the county's vaccination plans, may be enrolled in the study. However, we will not explicitly target pregnant women or ask about pregnancy. Vaccination offers will be determined by medical personnel from the county and CCRMC, separate from the study.

- Recruitment Process (sampling strategy)
    - Eligible adults will be invited to participate in the study via email, mail, and/or text.
    - CCRMC will provide us with a list of impaneled adult patients who are eligible for vaccination based on county prioritization categories and individual health status and who self-identify as African American/Black, White or Latino (irrespective of race). The list will be shared by CCHS via USC Marshall's box.com accounts and will be managed by Tom Chang.
    - We will randomly sample and invite adults from this list to participate in a baseline survey. Recruitment in this way will continue until we reach a goal of 10,000 baseline survey responses.

- Enrollment Process
    - Consent will occur through the baseline survey available via USC RedCAP and through the included consent documents.
    - We will also ask for HIPAA authorization so that we can link the survey data to information on vaccinations.

- Methods

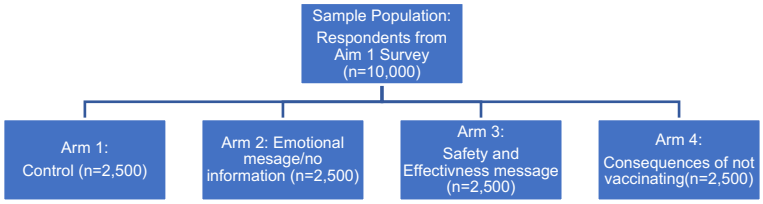
Our work will begin with a large online survey (N=10,000) of a random sample of the members of the county Medicaid managed care plan in Contra Costa County, CA. Contra Costa Health Plan (CCHP), has over 100,000 adult members. Over a quarter of adult members are Latino, a quarter non-Hispanic White and about 15% each are Black, Asian or of other/unknown race. Our sample will be drawn from CCHP members ages 18 and over who have not been previously vaccinated against COVID-19 and who have no contraindications to vaccination, as determined by county health plan medical staff. Because we are interested in testing race concordant messaging, we will also restrict to

members who are African American/Black, White or Latino (irrespective of race). Those of other/unknown race are excluded because they cannot be matched based on race to a messenger as are Asians because the group is comprised of populations that are both linguistically and culturally quite distinct. In particular, about a third of the "Asian" group is Filipino, a third Vietnamese, 25% Mandarin-speaking Chinese, 20% Cantonese-speaking Chinese, 15% Punjabi-speaking Indian, 10% Laotian, 10% Korean, and so on. As such, we do not think these populations can credibly be treated as one group for the purposes of studying race concordance and yet each group is individually too small to consider alone. Survey respondents will receive a $5 gift card for their time and be entered into a raffle for a $250 gift card.

In the survey, much of which we have previously piloted for a related project, we will capture rates of preventive health behaviors, including mask-wearing, hand washing, and, most importantly, willingness to vaccinate. Stratifying based on race/ethnicity, age-group and other characteristics predictive of vaccine take-up, we will randomize the 10,000 respondents to one of four arms:

1. Control arm [2,500]
2. Messaging/Information Arm 1: no information/emotional message [N=2,500]
3. Messaging/Information Arm 2: safety and effectiveness information [N=2,500]
4. Messaging/Information Arm 3: information on consequences of going unvaccinated].

Figure. Randomization Design



The information arms have been designed with the experimental literature on vaccination intentions in mind (see Brewer et al. 2017 for a review). That literature finds, among other things, that messages aimed at clarifying the negative outcomes of not getting vaccinated are much more effective at changing intentions than messages that try to correct misperceptions about vaccine safety. Within the arm 3 and arm 4 message groups, we will further randomize participants to race/ethnicity concordant/discordant video messages and to gender concordant/discordant messages. This intervention builds on recent evidence that race-concordant health care providers increase health screening take-up (Alsan et al. 2019).

Each of these four arms will be interacted with a financial incentive of $10 (N=2,500) or $50 (N=2,500) and, separately with a convenient link to the county public vaccine appointment scheduling system highlighted for participants (N=5,000).

The above treatments are designed to test the role of the following on vaccine take-up:

- Financial incentives [N=5,000] vs. no financial incentives [N=5,000]
    - 2,500 will be randomized to a $10 incentive and 2,500 to a $50 incentive

- Convenient scheduling link highlighted [N=5,000] vs. not [N=5,000]
- Messaging [N=7,500] vs not [2,500]
    - Message type: emotion [N=2,500] vs. safety and effectiveness [N=2,500] vs. consequences of not vaccinating [N=2,500]
- Race concordant [N=2,500] vs. race discordant messenger [N=2,500]
- Gender concordant [N=2,500] vs. gender discordant messenger [N=2,500]

These financial incentives of $10 or $50 are in line with the prior literature. For example, Bronchetti, Huffman, and Magenheim (2015) paid college students $30 for flu vaccinations in 2012. In addition, the $50 incentive is in-line with 2 hours of time at the minimum wage plus transportation costs. These incentives will be paid for with funding from J-PAL. While financial incentives for vaccination have faced some criticism (Largent and Miller 2021), prior work suggests small incentives can be quite effective (Bronchetti, Huffman, and Magenheim 2015). Given the urgency of the issue, we think it is crucial to test the effectiveness of financial incentives against other potential tools to improve vaccine take-up. We will also examine study impacts for subpopulations of interest identified in our baseline survey (e.g., groups at a high risk for adverse health outcomes or young adults who have high potential to be super-spreaders of COVID-19).

We understand that the IRB is concerned that the incentives for vaccination are not equal across participants in the incentive arm. However, this approach is fairly standard in behavioral economic studies and has been approved by many IRBs at peer institutions. We highlight just a few such health studies here but there are dozens of other relevant examples:

1. Alsan et al. (2019), which studied preventive health care among African American men, included a condition that randomly offered subjects incentives of $5 or $10 for selecting an influenza vaccination. These rewards were for intentions and were irrespective of actual vaccination. This study was approved by Stanford's IRB. The protocol is available in Alsan et al. (2018) https://doi.org/10.1257/rct.2497-2.0.

2. Bachireddy et al. (2019), which studied physical activity, compared 3 different 2-week incentive programs with rewards for daily steps taken. Incentives varied from $0.10 per 10,000 steps to $2 per 10,000 steps, a 20-fold difference, over the 2-week intervention period. This study was approved by the IRB at University of Pennsylvania.

3. Jones et al. (2019), which studied workplace wellness programs, offered varying levels of cash rewards ($100 vs. $200) to University of Illinois employees for completing a biometric screening and health risk assessment and an additional cash reward for completing each wellness activity ($25 vs. $75). The study was approved by the IRBs at University of Illinois Urbana Champaign, the University of Chicago and the National Bureau of Economic Research.

We believe our work is in line with these and many other studies. It is also extremely policy relevant given concern about vaccine take-up.

Our primary outcomes are vaccine take-up at one month and vaccine intentions at the time of survey. Secondary analysis will consider any vaccine take-up over longer time periods.

Overview of procedures to be used for

- Data collection tools
    - Baseline survey – Survey will be translated into Spanish and thus available in both Spanish and English for respondents to choose from in RedCAP.
    - Administrative data from CCRMC on COVID-19 tests, vaccinations, hospitalizations
- Vaccination appointments in Contra Costa have been open to all age groups since March 30, 2021.
- Research procedures will end once survey respondents have "received" an intervention. The research team will not take part in any delivery of care. Thus, any actual take-up of vaccinations will be subject to normal CCHS standard of care.
- Data Analysis

- Randomization

Randomization will be performed in the RedCAP system. In practice, the randomization will divide the sample into 60 possible conditions:

1. Control [N=625]
2. Control x $10 financial [N=312.5]
3. Control x $50 financial [N=312.5]
4. Control x link [N=625]
5. Control x $10 financial x link [N=312.5]
6. Control x $50 financial x link [N=312.5]
7. No information/Emotional (language concordant) [N=625]
8. No information/Emotional (language concordant) x $10 financial [N=312.5]
9. No information/Emotional (language concordant) x $50 financial [N=312.5]
10. No information/Emotional (language concordant) x link [N=625]
11. No information/Emotional (language concordant) x $10 financial x link [N=312.5]
12. No information/Emotional (language concordant) x $50 financial x link [N=312.5]
13. Safety and effectiveness (race concordant, male) [N=156.25]
14. Safety and effectiveness (race concordant, male) x $10 financial incentive [N=78.125]
15. Safety and effectiveness (race concordant, male) x $50 financial incentive [N=78.125]
16. Safety and effectiveness (race concordant, male) x link [N=156.25]

17. Safety and effectiveness (race concordant, male) x $10 financial incentive [N=78.125]
18. Safety and effectiveness (race concordant, male) x $50 financial incentive [N=78.125]
19. Safety and effectiveness (race concordant, female) [N=156.25]
20. Safety and effectiveness (race concordant, female) x $10 financial incentive [N=78.125]
21. Safety and effectiveness (race concordant, female) x $50 financial incentive [N=78.125]
22. Safety and effectiveness (race concordant, female) x link [N=156.25]
23. Safety and effectiveness (race concordant, female) x $10 financial incentive x link [N=78.125]
24. Safety and effectiveness (race concordant, female) x $50 financial incentive x link [N=78.125]
25. Safety and effectiveness (race discordant, male) [N=156.25]
26. Safety and effectiveness (race discordant, male) x $10 financial incentive [N=78.125]
27. Safety and effectiveness (race discordant, male) x $50 financial incentive [N=78.125]
28. Safety and effectiveness (race discordant, male) x link [N=156.25]
29. Safety and effectiveness (race discordant, male) x financial incentive x link [N=78.125]
30. Safety and effectiveness (race discordant, male) x financial incentive x link [N=78.125]
31. Safety and effectiveness (race discordant, female) [N=156.25]
32. Safety and effectiveness (race discordant, female) x $10 financial incentive [N=78.125]
33. Safety and effectiveness (race discordant, female) x $50 financial incentive [N=78.125]
34. Safety and effectiveness (race discordant, female) x link [N=156.25]
35. Safety and effectiveness (race discordant, female) x $10 financial incentive x link [N=78.125]
36. Safety and effectiveness (race discordant, female) x $50 financial incentive x link [N=78.125]
37. Consequences of going unvaccinated (race concordant, male) [N=156.25]
38. Consequences of going unvaccinated (race concordant, male) x $10 financial incentive [N=78.125]
39. Consequences of going unvaccinated (race concordant, male) x $50 financial incentive [N=78.125]
40. Conseqences of going unvaccinated (race concordant, male) x link [N=156.25]
41. Conseqences of going unvaccinated (race concordant, male) x $10 financial incentive x link [N=78.125]

42. Conseqences of going unvaccinated (race concordant, male) x $50 financial incentive x link [N=78.125]
43. Conseqences of going unvaccinated (race concordant, female) [N=156.25]
44. Conseqences of going unvaccinated (race concordant, female) x $10 financial incentive [N=78.125]
45. Conseqences of going unvaccinated (race concordant, female) x $50 financial incentive [N=78.125]
46. Conseqences of going unvaccinated (race concordant, female) x link [N=156.25]
47. Conseqences of going unvaccinated (race concordant, female) x $10 financial incentive x link [N=78.125]
48. Conseqences of going unvaccinated (race concordant, female) x $50 financial incentive x link [N=78.125]
49. Conseqences of going unvaccinated (race discordant, male) [N=156.25]
50. Conseqences of going unvaccinated (race discordant, male) x $10 financial incentive [N=78.125]
51. Conseqences of going unvaccinated (race discordant, male) x $50 financial incentive [N=78.125]
52. Conseqences of going unvaccinated (race discordant, male) x link [N=156.25]
53. Conseqences of going unvaccinated (race discordant, male) x $10 financial incentive x link [N=78.125]
54. Conseqences of going unvaccinated (race discordant, male) x $50 financial incentive x link [N=78.125]
55. Conseqences of going unvaccinated (race discordant, female) [N=156.25]
56. Consequences of going unvaccinated (race discordant, female) x $10 financial incentive [N=78.125]
57. Consequences of going unvaccinated (race discordant, female) x $50 financial incentive [N=78.125]
58. Consequences of going unvaccinated (race discordant, male) x link [N=156.25]
59. Consequences of going unvaccinated (race discordant, male) x $10 financial incentive x link [N=78.125]
60. Consequences of going unvaccinated (race discordant, male) x $50 financial incentive x link [N=78.125]

- Protection of Data

All identifiable data (names and either phone, email or physical address) will be available only for the purposes of 1) inviting study participants and 2) linking data. These data will be kept on secure password-protected USC Marshall servers and will only be accessible to Drs. Chang and Pramanik. Data sharing will occur through Marshall administered Box accounts. Box encrypts data at rest and in transit. Tom Chang will handle all matching of surveys and administrative data.

Name and address information, not linked to any health information, will also be made available to the minimum number of research staff needed to invite participants to our surveys.

Analytic datasets available to the research team will be limited datasets, without name, address, or any contact information. That data will be stored in a password protected shared study drive.

References

Alsan, Marcella, Owen Garrick and Grant Graziani. 2018. "The Oakland Men's Health Disparities Study." AEA RCT Registry. March 21. https://doi.org/10.1257/rct.2497-2.0

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Bronchetti ET, Huffman DB and Magenheim E. 2015. Attention, intentions, and follow-through in preventive health behavior: Field experimental evidence on flu vaccination. Journal of Economic Behavior & Organization, 116, 270–291. DOI: 10.1016/j.jebo.2015.04.003.

Damon Jones, David Molitor, Julian Reif, 2019. What do Workplace Wellness Programs do? Evidence from the Illinois Workplace Wellness Study, The Quarterly Journal of Economics, 134(4): 1747-1791 qjz023, https://doi.org/10.1093/qje/qjz023

Largent EA, FG Miller. 2021. Problems With Paying People to Be Vaccinated Against COVID-19
JAMA Published online January 6, 2021. PMID: **33404585**

Version: 1.1
Application Version Date: 6/1/2021

Date: Tuesday, June 1, 2021 4:21:06 PM Print Close

1. Project Identification Information

Title of the Protocol: COVID-19 and Preventive Health Behaviors (UP-21-00030)

Principal Investigator: Mireille Jacobson

Study Coordinator:

AM1.1. * Identifier for this Amendment:
Increase survey incentive

AM1.2. * Type of Amendment(s) (check all that apply):

Type	
☐	Editorial
☐	Drug or Device
☐	Enrollment Status Change
☐	Funding
☐	Informed Consent and/or Addenda
☐	Investigator's Brochure / Package Insert
☐	Locations
☐	Number of Subjects
☐	Procedures and/or Protocol
☐	Recruitment Materials
☐	Risks/Harms
☐	Study Personnel
☐	Subject Population
☑	**Subject Reimbursement / Compensation**

☐ Other

AM1.3. Will the changes you are making affect the accuracy of the study abstract?

○ Yes ● **No**

AM1.6. Has the risk/benefit ratio changed?

○ Yes ● **No**

14. Subject Reimbursement / Compensation

This screen is required if you indicated this amendment involves changes to Subject Reimbursement or Compensation policies or amounts. (Question 1.2.)

14. Please describe each of the changes to Subject Reimbursement and/or Compensation and provide a rationale for the change.
We would like to increase our survey incentive to $25 to address low take-up. We have included consent documents in both English and Spanish for a $25 survey incentive. We have made no changes to the study design itself.

You must make your changes in the body of the main study application by clicking on "Edit Modified Study" in the Amendment workspace. Please remember to revise any other information effected by this change. It is likely that changes to subject compensation will require updating consent documents (item 24).

99. Modified Study Link

To make your changes to the study specified in this amendment, please:

1. Click the Finish button in the menu bar above or below this form.
2. Click the Edit Amendment button on the left-side panel of the Amendment workspace.
3. Make your changes to the study application.
4. Make sure you click the save button to save the changes you made.
5. When you done with changes in Edit Amendment , you need to submit the amendment to the IRB.

APPENDIX B: Informed Consent Documents and HIPAA Authorization

University of Southern California
USC Davis School of Gerontology
3715 McClintock Ave, Los Angeles, CA 90089

INFORMED CONSENT FOR RESEARCH

Study Title: COVID-19 and Preventive Health Behaviors

Principal Investigator: Mireille Jacobson, Ph.D.

Department: USC Leonard Davis School of Gerontology

INTRODUCTION

We invite you to take part in a research study. Please take as much time as you need to read the consent form. You may want to discuss it with your family, friends, or your personal doctor. If you find any of the language difficult to understand, please ask questions. You can contact the study lead, Mireille Jacobson by phone or email: tel: 213-986-6076 or email: mireillj@usc.edu. If you decide to participate, you will be asked to sign this form. A copy of the signed form will be provided to you for your records.

KEY INFORMATION

The following is a short summary of this study to help you decide whether you should participate. More detailed information is listed later in this form.

1. Being in this research study is voluntary–it is your choice.

2. You are being asked to take part in this study so that Contra Costa County can better understand COVID-19 vaccine uptake. The purpose of this study is to analyze behaviors in relation to COVID-19, including vaccinations. Procedures will include the completion of a baseline survey. Your participation in the baseline survey will last approximately 15 minutes and is completely voluntary.

3. If you consent to be part of this study, information on health care, received at Contra Costa Regional Medical Center (CCRMC) or otherwise provided by Contra Costa Health Services or the County of Contra Costa, including COVID-19 tests and test results and COVID-19 vaccination status, may be shared with the study investigators. The investigators will keep your data secure and will not share your information with anyone outside the study team. All your information will be kept confidential.

4. Some people who participate in this study will be randomly selected to receive additional information about COVID-19 vaccines. Some people who participate will be randomly selected to receive gift certificates for being vaccinated that vary between $10 and $50. We will contact you if you are selected for either of these.

5. There are risks from participating in this study. The most common risks are that some of the survey questions may make the participant feel uneasy or embarrassed. There is also a small risk that people not connected with the study will learn the participants identity or their personal information. More detailed

information about the risks of this study can be found under the "Risk and Discomfort" section.

5. You may not receive any direct benefit from taking part in this study. However, your participation in this study may help us learn how to better manage the COVID-19 pandemic in Contra Costa County.

6. If you decide not to participate in this research, your other choices may include: not participate in the study.

DETAILED INFORMATION

PURPOSE

The purpose of this study is to better understand COVID-19 vaccinations and other preventive behaviors taken to mitigate the spread of the disease. This research is designed to help Contra Costa better understand the COVID-19 pandemic and shape and improve its efforts to better serve the community. About 10,000 participants will take part in the study.

PROCEDURES

If you decide to take part, you will be asked to complete a baseline survey on your phone, tablet or internet connected computer. The surveys take about 15 minutes to complete. The surveys ask you about COVID-19, how it has affected your day to day life, as well as about your life more generally. Your survey responses may be linked to your COVID-19 test and vaccination information and possibly other data already captured by the county health system. However, all your information will remain confidential and will be anonymized for research purposes.

1. You will complete a 15-minute baseline survey.
2. Your survey data may be linked to data from Contra Costa Health Services and shared with the study investigators.
3. Some people who participate will be randomly selected to receive additional information about the COVID-19 vaccine.
4. Some people who participate will be randomly selected to receive gift certificates for being vaccinated of $10 or $50. We will contact you if you are selected for these.

RISKS AND DISCOMFORTS

Possible risks and discomforts you could experience during this study include:

Surveys/Questionnaires/Interviews: Some of the questions may make you feel uneasy or embarrassed. You can choose to skip or stop answering any questions you don't want to.

Breach of Confidentiality: There is a small risk that people who are not connected with this study will learn your identity or your personal information.

BENEFITS

There are no direct benefits to you from taking part in this study. However, your participation in this study may help us learn more about the current COVID-19 (coronavirus) pandemic in Contra Costa County to improve county-wide efforts to contain the virus.

PRIVACY/CONFIDENTIALITY

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who are required to review this information. Information about this study will be posted at ClinicalTrials.gov. We may publish the information from this study in journals or present it at meetings. We will not use your name on ClinicalTrials.gov, in any journal articles, or in any meeting presentations.

The University of Southern California's Institutional Review Board (IRB) may review your records. Organizations that may also inspect and copy your information include: the Contra Costa County Regional Medical Center's Institutional Review Committee (IRC) and the National Bureau of Economic Research's IRB. The IRB/IRC reviews and monitors research studies to protect the rights and welfare of research subjects.

Your information that is collected as part of this research will be used or distributed for future research studies without your additional informed consent. Any information that identifies you (such as your name) will be removed from your private information before being shared with others.

ALTERNATIVES

An alternative would be to not participate in this study.

PAYMENTS

If you complete the baseline survey, you will receive a gift card of $25 for your time and be entered into a drawing for a $250 gift card. In total, we will raffle off 20 gift cards valued at $250 each. Some people who participate will be randomly selected to receive gift certificates for being vaccinated between $10 and $50.

COST

There are no costs related to participation.

VOLUNTARY PARTICIPATION

It is your choice whether to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can continue to collect data from your records. If you agree, this data will be handled the same as the research data. No new information will be collected about you or from you by the study team without your permission.

Your personal information, including any identifiable information, that has already been collected up to the time of your withdrawal will be kept and used to guarantee the integrity of the study, to determine the safety effects, and to satisfy any legal or regulatory requirements.

CONTACT INFORMATION

If you have questions, concerns, complaints, or think the research has hurt you, talk to the study investigator at

Mireille Jacobson, tel: 213-986-6076 or email: mireillj@usc.edu

This research has been reviewed by the USC Institutional Review Board (IRB). The IRB is a research review board that reviews and monitors research studies to protect the rights and welfare of research participants. Contact the IRB if you have questions about your rights as a research participant or you have complaints about the research. You may contact the IRB at (323) 442-0114 or by email at irb@usc.edu.

STATEMENT OF CONSENT

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing to take part in this study.

☐ **I agree to participate**

☐ **I do NOT agree to participate**

Principal Investigator:	Mireille Jacobson
Study Title:	COVID-19 and Preventive Health Behaviors
IRB #:	UP-21-00030

HIPAA AUTHORIZATION TO USE CONTRA COSTA HEALTH SERVICES (CCHS) HEALTH INFORMATION FOR RESEARCH

1. Purpose of this Form:

A federal law known as the Health Insurance Portability and Accountability Act (HIPAA) protects how your health information is used. HIPAA generally does not allow your health information to be used or released for research purposes without your written permission. Health information protected under the law includes: medical and dental records, bills or other payment records for health care received, tissue samples, x-rays, laboratory results and any other health information that identifies you. State laws also protect how your health information may be used.

By signing this form, you are allowing your health care providers (for example, physicians, dentists, hospitals, clinics) to share your health information with the researchers and others involved in this research study for the uses described below and also described in the informed consent.

2. Who May Release Your Health Information:

This document permits (i) Contra Costa Health Services to release health information about you to (ii) the researchers for the research purposes described in this document and the informed consent.

3. What Health Information Will Be Used:

Contra Costa Health Services is permitted to use and release (i) all health information that is created during this research study; and all of your health information that the health care provider has in his or her possession, but does not include HIV test results, mental health diagnosis and treatment records, and drug or alcohol treatment records.

4. How Your Health Information Will Be Used:

Your health information may be shared with the following individuals or entities for the following purposes:

Researchers (those individuals in charge of the study), research staff, and students to conduct the research described in the informed consent and other activities related to the research, such as conducting safety analyses.

- The research sponsors, J-PAL North America and the National Bureau of Economic Research, and their authorized representatives, business partners, clinical research organizations and affiliates for the purposes described in the informed consent and for other activities related to the research, such as assessing the safety or efficacy of the drug, device or treatment included in the study, improving designs of future studies or obtaining approval for new drugs, devices or health care products.

- The USC Institutional Review Boards that review research involving human subjects in accordance with regulations;

- USC's clinical trial organization that supports clinical trials administration at USC,

- Other USC offices involved in regulatory compliance, including the Offices of General Counsel and Compliance,

- U.S. government agencies, such as the Food and Drug Administration and the Office for Human Research Protections, government agencies from other countries, and others who are authorized by law to review or oversee this research.

5. <u>Creation of a Research Database</u>:

The following is an optional research activity. You can choose whether or not to participate in these activities and it will not affect your ability to participate in the main research study. Please initial on the line below to give your specific permission to this activity.

_____ Researchers will often study existing health information from large groups of patients in order to test or validate theories that the researcher develops. By initialing above, you allow the USC research team to put your health information in a research database or repository for future research purposes. The USC Institutional Review Board still may review how the researcher uses or releases your health information for future research purposes.

This section of the Authorization will remain in effect indefinitely unless you revoke (cancel) it as described below.

6. **Scope of this Authorization:**

The USC research team will use and release your health information for the purposes described in this authorization and the informed consent or as otherwise permitted by law. However, health information that is shared with others outside USC may not be protected by HIPAA once it is released. Certain health information may still be protected under state law.

7. **Right to Deny Access to Health Information:**

You may not be permitted to access (review or copy) your health information created during this research study while the research study is in progress. You may be entitled to access your health information once the research study is completed.

8. **Term of this Authorization:**

Except for database research, this authorization expires 25 years from the date the study is completed or terminated.

9. **Refusal to Sign/Right to Revoke:**

You must sign this Authorization in order to participate in this research. You may change your mind and revoke (withdraw or cancel) this authorization and your participation in this research study at any time. To do so, your revocation must be sent in writing to the Principal Investigator and include: (1) the title of the research study; and (2) your name and telephone number or address. Please send the revocation to the following:

Professor Mireille Jacobson
3715 McClintock Ave
Los Angeles, CA 90089

You will not be permitted to participate in the research and health information that identifies you will no longer be collected as of the date the Principal Investigator receives

your revocation. However, we may still use and share health information about you that has already been obtained as necessary in order to maintain the integrity of the research study. Also, if the law requires it, the researchers, sponsor, and government agencies may continue to look at your records to review the quality or safety of the study.

10. Questions Regarding Your Privacy Rights:

Please contact the USC Office of Compliance by telephone at 213-740-8258 or email at compliance@usc.edu if you have questions about your privacy rights.

Agreement:

I have read (or someone has read to me) the information provided above. I have been given the opportunity to ask questions and all of my questions have been answered to my satisfaction. By signing below, I agree that my health information may be used as described in this form.

Name of Participant	Signature	Date Signed

University of Southern California
USC Davis School of Gerontology
3715 McClintock Ave., Los Angeles, CA 90089

AUTORIZACIÓN PARA PARTICIPAR EN UN ESTUDIO DE INVESTIGACIÓN

Título del estudio: COVID-19 y Comportamiento de Salud Preventivos

Investigadora principal: Mireille Jacobson, Ph.D.

Departamento: USC Leonard Davis School of Gerontology

INTRODUCCIÓN

Te invitamos a participar en un estudio de investigación. Tómate el tiempo que necesites para leer el formulario de consentimiento. Es posible que desees discutirlo con tu familia, amigos o tu médico personal. Si encuentras que alguno de los idiomas es difícil de entender y tienes dudas, puedes comunicarte con la directora del estudio, Mireille Jacobson, por teléfono o correo electrónico: 213-986-6076 o correo electrónico: mireillj@usc.edu. Si decides participar, se te pedirá que firmes este formulario. Se te proporcionará una copia del formulario firmado para tus registros.

INFORMACIÓN IMPORTANTE

El siguiente es un breve resumen de este estudio para ayudarte a decidir si quieres participar. Información detallada encontraras más adelante en este formulario.

1. Es totalmente voluntario participar en este estudio, simplemente es tu elección.

2. Se te está pidiendo que participes en este estudio para que el Condado de Contra Costa pueda entender mejor el comportamiento de la vacunacíon COVID-19. El propósito de este estudio es analizar los comportamientos en relación con COVID-19, incluidas las vacunas. Los procedimientos incluirán la realización de una encuesta. Tú participación en este estudio durará aproximadamente 15 minutos y es totalmente voluntario.

3. Si aceptas formar parte de este estudio, la información sobre la atención médica, recibida en el Centro Médico Regional de Contra Costa (CCRMC) o proporcionada de otra manera por Contra Costa Health Services o el Condado de Contra Costa incluidas las pruebas COVID-19 y los resultados de las pruebas y COVID -19 estado de vacunación, se puede compartir con los investigadores del estudio. Los investigadores mantendrán tus datos seguros y no compartirán tu información con nadie fuera del equipo del estudio. Toda tu información se mantendrá confidencial.

4. Algunas personas que participan en este estudio serán seleccionadas al azar para recibir información adicional sobre las vacunas COVID-19. Algunas personas que participen serán seleccionadas al azar para recibir una tarjeta de regalo por ser vacunados que varían entre $10 y $50. Nos comunicaremos contigo si eres seleccionado para alguno de estos.

5. Existen algunos riesgos por participar en este estudio. Los riesgos más comunes son que algunas preguntas de la encuesta pueden hacer que el participante se sienta incómodo o avergonzado, y existe un pequeño riesgo de que algunas personas que no están relacionadas con el estudio conozcan la identidad de los participantes o su información personal.

5. Tú participación en este estudio puede ayudarnos a aprender cómo manejar mejor la pandemia de COVID-19 en el Condado de Contra Costa.

6. Si decides no participar en esta investigación, puedes simplemente no participar en el estudio.

INFORMACIÓN DETALLADA

PROPÓSITO

El propósito de este estudio es comprender mejor las vacunas COVID-19 y los comportamientos adoptados para mitigar la propagación de la enfermedad. Está investigación está diseñada para ayudar a Contra Costa a comprender mejor la pandemia de COVID-19 y dar forma y mejorar sus esfuerzos para servir mejor a la comunidad. Alrededor de 10.000 participantes participarán en el estudio.

PROCEDIMIENTOS

Si decides participar, se te pedirá que completes una encuesta en tú teléfono, tableta o computadora conectada a Internet. Las encuestas tardan entre 15 minutos en completarse. Las encuestas te preguntan sobre COVID-19, cómo te ha afectado tu vida cotidiana, así como sobre tu vida en general. Las respuestas de tu encuesta pueden estar vinculadas a la información de tu pruebas de COVID-19 y la información de vacunacíon y posiblemente a otros datos ya capturados por el sistema de salud del condado. Sin embargo, toda tu información permanecerá confidencial y se mantendrá anónima para fines de investigación.

1. Completarás una encuesta inicial de 15 minutos.
2. Los datos de tu encuesta pueden estar vinculados a datos de Contra Costa Health Services y compartidos con los investigadores del estudio.
3. Algunas personas que participen en este estudio serán seleccionadas al azar para recibir información adicional sobre las vacunas COVID-19.
4. Algunas personas que participen serán seleccionadas al azar para recibir una tarjeta de regalo por ser vacunados que varían entre $10 y $50. Nos comunicaremos contigo si eres seleccionado para alguno de estos.

RIESGOS E INCOMODIDADES

Los posibles riesgos y molestias que podrías experimentar durante este estudio incluyen:

Encuestas/ Cuestionarios/ Entrevistas: algunas de las preguntas pueden hacerte sentir incómodo o avergonzado. Puedes optar por omitir o dejar de responder cualquier pregunta que no desees.

Incumplimiento de la confidencialidad: existe un pequeño riesgo de que algunas personas que no están relacionadas con este estudio conozcan tu identidad o tu información personal.

BENEFICIOS

No hay beneficios directos para ti al participar en este estudio. Sin embargo, tu participación en este estudio puede ayudarnos a aprender más sobre la pandemia actual de COVID-19 (coronavirus) en el Condado de Contra Costa para mejorar los esfuerzos de todo el condado para contener el virus.

PRIVACIDAD / CONFIDENCIALIDAD

Mantendremos la confidencialidad de tus registros para este estudio hasta donde lo permita la ley. Sin embargo, si la ley nos exige hacerlo, divulgaremos información confidencial sobre tí. Se realizarán esfuerzos para limitar el uso y la divulgación de tu información personal, incluidos el estudio de investigación y los registros médicos, a las personas que deben revisar esta información. La información sobre este estudio se publicará en ClinicalTrials.gov. Podemos publicar la información de este estudio en revistas o presentarla en reuniones. No usaremos tu nombre en ClinicalTrials.gov, en ningún artículo de revista o en presentaciones de reuniones..

La Junta de Revisión Institucional (IRB) de la Universidad del Sur de California puede revisar tus registros. Las organizaciones que también pueden inspeccionar y copiar tu información incluyen: el Comité de Revisión Institucional (IRC) del Centro Médico Regional del Condado de Contra Costa y la IRB del National Bureau of Economic Research (NBER). El IRB / IRC revisa y supervisa los estudios de investigación para proteger los derechos y el bienestar de los sujetos de investigación.

Tu información que se recopilará como parte de esta investigación se utilizará o distribuirá para futuros estudios de investigación sin tu consentimiento adicional. Cualquier información que te identifique (como tu nombre) será eliminada de su información privada o muestras antes de ser compartida con otros.

ALTERNATIVAS

Una alternativa sería no participar en este estudio.

Pagos

Recibirá una tarjeta de regalo de $25 por la encuesta y entrarás a una rifa de $250 en una tarjeta de regalo. En total, sortearemos 20 tarjetas de regalo valoradas en $250 cada una. Algunas personas que participen serán seleccionadas al azar para recibir una tarjeta de regalo por ser vacunados que varían entre $10 y $50.

COSTO

No hay costos relacionados con la participación.

PARTICIPACION VOLUNTARIA

Es tu elección participar. Si eliges participar, puedes cambiar de opinión y abandonar el estudio en cualquier momento. Negarse a participar o suspender tu participación no implicará penalización o pérdida de beneficios a los que tiene derecho de otra manera.

Si dejas de participar en la investigación, es posible que los datos ya recopilados no se eliminen de la base de datos del estudio. Se te preguntará si el investigador puede continuar recopilando datos de tus registros. Si estás de acuerdo, estos datos se manejarán igual que los datos de la investigación. El equipo del estudio no recopilará información o muestras nuevas sobre ti o de ti sin tu permiso.

Puede ser que el estudio, después de que hayas decidido dejarlo, necesite comunicarte de cualquier evento de seguridad que pueda haber experimentado debido a tu participación a todas las entidades involucradas en el estudio. Tu información personal, que incluya cualquier información que te pueda identificar, y que se haya recopilado hasta el momento de tu retiro, se conservará y utilizará a para garantizar la integridad del estudio, determinar los efectos de seguridad y satisfacer cualquier requisito legal o reglamentario.

INFORMACIÓN DEL CONTACTO

Si tienes preguntas, inquietudes, quejas o crees que la investigación te ha perjudicado, habla con la investigadora del estudio:

Mireille Jacobson, tel: 213-986-6076 o correo electrónico: mireillj@usc.edu

Esta investigación ha sido revisada por la Junta de Revisión Institucional (IRB) de la USC. El IRB es una junta de revisión de investigación que revisa y monitorea los estudios de investigación para proteger los derechos y el bienestar de los participantes de la investigación. Ponte en contacto con el IRB si tienes preguntas sobre tus derechos como participante de la investigación o si tienes quejas sobre la investigación.

University of Southern California
USC Davis School of Gerontology
3715 McClintock Ave., Los Angeles, CA 90089

Puede comunicarse con el IRB al (323) 442-0114 o por correo electrónico a irb@usc.edu.

DECLARACIÓN DE CONSENTIMIENTO

He leído (o alguien me ha leído) la información proporcionada anteriormente. Se me ha dado la oportunidad de hacer preguntas. Todas mis preguntas han sido respondidas. Al firmar este formulario, acepto participar en este estudio.

☐ **Acepto participar**

☐ **NO estoy de acuerdo en participar**

Investigador principal:	Mireille Jacobson
Título del estudio:	COVID-19 y Comportamiento de Salud Preventivos
N.° IRB.	UP-21-00030

AUTORIZACIÓN DE CONSENTIMIENTO CON LA LEY HIPAA PARA UTILIZAR INFORMACIÓN DE SALUD DE CONTRA COSTA HEALTH SERVICES CON FINES DE INVESTIGACIÓN

1. Finalidad de este formulario:

La ley federal denominada Ley de Portabilidad y Responsabilidad de Seguros de Salud (HIPAA, por sus siglas en inglés) protege la forma en que se utiliza su información de salud. Por lo general, la ley HIPAA no permite que su información de salud se utilice o divulgue con fines de investigación sin su autorización por escrito. La información sobre la salud protegida por la ley incluye: historias clínicas o registros dentales, facturas u otros registros de pago por atención de salud recibida, muestras de tejido, radiografías, resultados de análisis clínicos y cualquier otra información de salud que lo identifique como persona. Las leyes estatales también protegen el modo en que se puede utilizar su información de salud.

Mediante su firma en este formulario, usted autoriza a sus proveedores de atención de salud (por ejemplo, médicos, dentistas, hospitales, clínicas) a compartir su información de salud con los investigadores y demás personas que formen parte de este estudio de investigación para los usos que se detallan a continuación y que también se describen en el consentimiento informado.

2. Quién puede difundir su información de salud:

Este documento permite que (i) Contra Costa Health Services a continuación difundan información de salud sobre usted con (ii) los investigadores de los fines de investigación descritos en este documento y en el consentimiento informado:

3. Qué información de salud se utilizará:

Contra Costa Health Services tienen permiso para utilizar y divulgar (i) toda la información de salud que se cree durante este estudio de investigación, y toda la información de salud que el proveedor de atención de salud tenga en su posesión, pero que no incluye resultados sobre la prueba del VIH, registros de diagnósticos y tratamientos de salud mental ni registros de tratamientos por alcohol o drogas

4. De qué manera se utilizará su información de salud:

Es posible que su información de salud se comparta con las siguientes personas o entidades con los siguientes fines:

- Investigadores (personas a cargo del estudio), personal de la investigación, estudiantes a fin de realizar la investigación descrita en el consentimiento informado y otras actividades relacionadas con la investigación, como llevar a cabo análisis de seguridad.

- Los patrocinadores de la investigación, J-PAL North America and the National Bureau of Economic Research, y sus representantes autorizados, socios comerciales, organizaciones de investigación clínica y afiliadas con los fines descritos en el consentimiento informado y para otras actividades relacionadas con la investigación, como la evaluación de la seguridad o la eficacia del medicamento, el dispositivo o tratamiento incluidos en el estudio, la mejora de los diseños de estudios futuros o la obtención de aprobación para nuevos medicamentos, dispositivos o productos de atención de salud.

- Las Juntas de Revisión Institucionales de USC que revisan las investigaciones con seres humanos de conformidad con las regulaciones.

- La organización de ensayos clínicos de USC que respalda la administración de ensayos clínicos en USC.

- Otras oficinas de USC involucradas en cuestiones de cumplimiento de las regulaciones, incluidas las Oficinas del Consejero Jurídico y Cumplimiento.

- Entidades gubernamentales de los EE. UU., como la Administración de Medicamentos y Alimentos (FDA, por sus siglas en inglés) y la Oficina para la Protección de los Seres Humanos en la Investigación (OHRP, por sus siglas en inglés), entidades gubernamentales de otros países, y otros que están autorizados por ley a revisar o supervisar esta investigación.

5. <u>Creación de una base de datos de investigación</u>:

La actividad de investigación que se presenta a continuación es opcional. Puede elegir si quiere participar o no en estas actividades y su decisión no afectará su capacidad de participar en el estudio de investigación principal. Escriba sus iniciales en la línea que aparece a continuación si desea conceder su permiso específico para esta actividad.

_____ Con frecuencia, los investigadores estudiarán la información de salud existente de grandes grupos de pacientes con el propósito de probar o validar las teorías que desarrolla el investigador. Al escribir sus iniciales más arriba, usted autoriza al equipo de investigación de USC a incluir su información de salud en una base de datos o almacén de investigación con la intención de realizar investigaciones futuras. La Junta de Revisión Institucional de USC puede revisar el modo en que el investigador utiliza o divulga su información de salud para investigaciones futuras.

Esta sección de la autorización permanecerá en vigencia indefinidamente a menos que usted revoque (cancele) esta autorización según se describe a continuación.

6. <u>Alcance de esta autorización:</u>

El equipo de investigación de USC solamente puede utilizar y divulgar su información de salud con los fines descritos en esta autorización y en el consentimiento informado o conforme a lo permitido por la ley. Sin embargo, es posible que la información de salud que se comparta con otros ajenos a USC no esté protegida por la ley HIPAA una vez que se haya divulgado. Cierta información de salud puede seguir estando protegida en virtud de la ley estatal.

7. <u>Derecho a denegar el acceso a la información de salud:</u>

Es posible que no se le permita consultar (revisar o copiar) su información de salud creada durante este estudio de investigación mientras el estudio de investigación se

esté llevando a cabo. Es posible que tenga derecho a tener acceso a su información de salud una vez que el estudio de investigación haya finalizado.

8. Plazo de esta autorización:

Excepto por la búsqueda en la base de datos, esta autorización vence en 25 años a partir de la fecha en que se complete o finalice el estudio.

9. Negación a firmar/derecho a revocar:

Debe firmar esta autorización para participar en esta investigación. Usted puede cambiar de parecer y revocar (retirar o cancelar) esta autorización y su participación en este estudio de investigación en cualquier momento. Para hacerlo, su revocación debe enviarse por escrito al Investigador Principal y debe incluir: (1) el título del estudio de investigación; y (2) su nombre y número de teléfono o dirección. Envie la revocación a:

Profesora Mireille Jacobson

3715 McClintock Ave

Los Angeles, CA 90089

No se le permitirá participar en la investigación y dejaremos de recopilar su información de salud que le identifique a partir de la fecha en que el Investigador Principal reciba su revocación. Sin embargo, podremos seguir usando y compartiendo la información de salud sobre usted que ya habíamos obtenido según sea necesario para mantener la integridad del estudio de investigación. Además, si la ley lo exige, los investigadores, el patrocinador y las entidades gubernamentales pueden continuar utilizando sus registros para revisar la calidad o la seguridad del estudio.

10. Preguntas con respecto a sus derechos de privacidad:

Si tiene preguntas acerca de sus derechos de privacidad, comuníquese con la Oficina de Cumplimiento (Office of Compliance) de USC por teléfono al 213-740-8258 o por correo electrónico a compliance@usc.edu.

Consentimiento:

He leído (u otra persona me leyó) la información que figura más arriba. Me han brindado la oportunidad de hacer preguntas y todas mis preguntas han sido respondidas a mi entera satisfacción. Con mi firma a continuación, acepto que mi información de salud se utilice según se detalla en este formulario.

Nombre del participante	Firma	Fecha de firma

APPENDIX C: MOP Modifications Log

Date Modified	Version #	Section #s	Page #s	Brief Summary
06/03/2021	1.1	Section 5.0; Appendix A; Appendix B	Pages 4; 48-53; 59-63	Increase in baseline survey incentive (from $5 to $25), to include IRB-approved protocol amendment and revised informed consent documents.