

Date: 2/16/22  
Principal Investigator: Kathleen Page  
Application Number: IRB00307482

## JHM IRB - eForm A – Protocol

- Use the section headings to write the JHM IRB eForm A, inserting the appropriate material in each. If a section is not applicable, leave heading in and insert N/A.
- When submitting JHM IRB eForm A (new or revised), enter the date submitted to the field at the top of JHM IRB eForm A.

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### 1. Abstract

- a. Provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.

Latinos are among the most heavily impacted communities by the Covid-19 pandemic. To promote COVID-19 testing and reduce disparities in the Latino community JH faculty partnered with Esperanza Center, the Sacred Heart Church, and community members in Baltimore to: 1. Establish a bilingual hotline that connects patients to COVID-19 testing at JHHS, 2. Implement community based testing at the Sacred Heart Church, 3. Develop a social marketing campaign and website to provide reliable COVID- 19 information and testing options. This intervention relied heavily on bilingual and bicultural navigators who connected patients who tested positive for COVID-19 to clinical follow up, isolation resources (e.g. cash assistance, food delivery, isolation hotel), antibody treatment if indicated, and testing for close contacts. An operational (Q/A) assessment of this intervention is ongoing (IRB00252774).

We have obtained NIH funding (3R01DA045556-04S1) for this project under the RADx initiative (radxup.org) and are required to collect common data elements for individuals who agree to participate in a survey. This IRB submission is to conduct a survey study related to COVID-19 testing and vaccination among Latinos. A limited dataset will be shared with the RADx-UP Coordination and Data Collection Center (CDCC) at Duke University and with the NIH under executed Data Use Agreements.

### 2. Objectives (include all primary and secondary objectives)

The objectives of this study are:

- 1) To identify the social determinants that impact COVID-19 risk  
*H1: COVID-19 risk is associated with immigration-related factors that lead to higher social vulnerability*
- 2) To identify structural and behavioral barriers and facilitators to access and uptake of COVID-19 testing and vaccination  
*H2: Language and culturally-congruent COVID-19 testing and vaccination services provided in the community enhance uptake of services for Latinos*

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**3. Background** (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

Latinos in the US are three times more likely to be hospitalized and more than twice as likely to die from COVID-19 than non-Hispanic (NH) whites. We have established a coalition of faith leaders (BUILD), community organizations (Casa de Maryland and Comité Latino), community clinics (Esperanza Center), and governmental organizations (Mayor's Office of Immigrant Affairs and the Baltimore City Health Department). Together, we developed and implemented a culturally and linguistically competent COVID-19 testing project, "Vive Sin Duda" (Live Without Doubt), which includes a Spanish language hotline, website, and social media campaign that links people to a community testing site. Demand for COVID-19 testing has declined with vaccination, but positivity rates remain high among Latinos who get tested through our program, highlighting the continued need to enhance testing in at-risk communities. For many low-income Latinos, access to conventional healthcare facility-based testing is hampered by lack of health insurance, difficulty in navigating the health system, immigration status, language barriers, stigma, lack of trust in healthcare institutions, and other social, economic, and cultural concerns. The goal of this survey study is to explore the social determinants that impact COVID-19 risk, as well as access and uptake of COVID-19 testing and vaccination.

**4. Study Procedures**

- a. Study design, including the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care).

Participants will be recruited through a convenience sampling from venues frequented by Latinos, such as select streets, outside venues, and community sites.

Recruiters will be study team members/research assistants (RA) fluent in Spanish with experience in outreach with this population. As part of our COVID-19 vaccine outreach, our team has identified areas and streets where Latinos congregate. Study team members/RA, working in pairs, will approach individuals who might be eligible for this study and verbally inform them about the opportunity to participate in the survey. For street outreach, the RAs will go to these areas (for example, frequently used laundry mats, the Home Depot, etc) and approach potential participants individually to offer participation in the study. It is anticipated that approximately 20% of the sample size will be from street outreach, and the rest from community sites. If an individual would like to participate, the RA will screen the individuals for eligibility. If an individual would like to participate, the RA will screen the individuals for eligibility. Eligibility criteria will include: 1) being age 18 years or older, 2) being Hispanic/Latino, and 3) living in Maryland. Exclusion criteria includes: 1) Prior participation in this survey study. If the eligibility is determined, the RA will review the study and obtain oral consent. After providing the oral consent, participants will self-administer a survey programmed in Redcap on a password protected tablet. Participants will also have the option to complete the survey in paper form if they prefer. RA will provide assistance upon request.

- b. If your study involves data/biospecimens from participants enrolled under other research studies with a written consent or under a waiver of consent, please list the IRB application numbers for those studies. Please note: Certificate of

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Confidentiality (CoC) protections applied to the data in source studies funded by NIH or CDC will extend to this new study if the funding was active in 2016. If this situation applies, Section 36, question 6 in the application will need to be answered “Yes” and “Hopkins Faculty” should be selected in question 7. No other documents are required.

- c. Study duration and number of study visits required of research participants.

Study duration will be 12 months and research participants have one study visit.

- d. Blinding, including justification for blinding or not blinding the trial, if applicable.

N/A

- e. Justification of why participants will not receive routine care or will have current therapy stopped.

N/A

- f. Justification for inclusion of a placebo or non-treatment group.

N/A

- g. Definition of treatment failure or participant removal criteria.

N/A

- h. Description of what happens to participants receiving therapy when study ends or if a participant’s participation in the study ends prematurely.

N/A

- i. If biological materials are involved, please describe all the experimental procedures and analyses in which they will be used.

N/A

## **5. Inclusion/Exclusion Criteria**

Eligibility criteria will include: 1) being age 18 years or older, 2) being Hispanic/Latino, and 3) living in Maryland. Exclusion criteria: 1) Prior completion of this survey, and 2) not meeting inclusion criteria.

## **6. Drugs/ Substances/ Devices: N/A**

- a. The rationale for choosing the drug and dose or for choosing the device to be used.  
b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed.

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- c. Justification and safety information if non-FDA approved drugs without an IND will be administered.

## **7. Study Statistics**

- a. Primary outcome variable.

COVID-19 testing uptake, which will be assessed through self-reported recent testing, including knowing the results of the test and the source of the last testing (e.g., clinic-based, local health department-based, community-based, home-based). For individuals who never got tested, questions include the history of any attempt to get tested, willingness to take the COVID-19 test.

- b. Secondary outcome variables.

COVID-19 vaccine uptake, which will be assessed by self-report of COVID-19 vaccination histories, including vaccination dates and locations.

- c. Statistical plan including sample size justification and interim data analysis.

Logistic regression models will be used to assess demographic, social and structural factors associated with COVID-19 testing and vaccine uptake. Subgroup analyses will be conducted, stratified by immigration-related factors, such as country of origin, English proficiency.

- d. Early stopping rules.

None

## **8. Risks**

- a. Medical risks, listing all procedures, their major and minor risks and expected frequency.

No medical risks are expected in this study.

- b. Steps taken to minimize the risks.

Our team has extensive experience of working with underserved and vulnerable populations including Latino and immigrant communities. We have developed numerous protocols to ensure that risks are minimized during recruitment and assessment activities. Participants are informed that they may withdraw from the study at any time if they feel uncomfortable. All individuals involved in human subjects research are supervised by the PI and the Study Coordinator and receive individualized quality assurance reports on a bi-weekly basis. In addition, monthly supervision meetings are held with recruitment and assessment staff to discuss quality assurance and human subjects' protections.

All project members are required to complete the Protection of Human Subjects Computer-based Training and Education program, which was developed in response to the National Institutes of Health directive requiring training on Human Subjects Protection. Utmost care will be taken when contacting participants about enrollment, participation and study compensation. Study staff will only talk to the participant directly unless the participant has authorized staff to leave a message. Participants provide identifiable information which will be kept in the password-

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protected Locator Information & Participation Database. All personal information about each participant is kept separate from the participant's ID number. We maintain a master list that links code number and identified information. The linkage between code number and identifiable information is maintained in a separate password-protected database accessible only by the PIs and selected designees. The master list must be retained in order for the payment of study compensation, but it will be destroyed at the completion of the study.

c. Plan for reporting unanticipated problems or study deviations.

Unanticipated problems will include adverse events (AEs) and serious adverse events (SAEs). The research staff will report problems or study deviations to the PIs during weekly meeting. SAEs will be reported to the PI within 24 hours orally or by email. Breaches of confidentiality would also be considered an adverse event.

The PI will report unanticipated problems or study deviations that involve risks to participants or others promptly to the JHM IRB in accordance with Organization Policy. Minor problems and protocol deviations (which pose no risk to subjects or others) will be reported in annual protocol continuing review.

Participants will be reminded to report any physical or social harm to the study staff immediately, so that participants may receive counseling or other assistance. When an adverse event is reported to the study staff, the staff investigates the details of the event and reaches a determination as to whether occurrence of the event was related to participation in the study.

d. Legal risks such as the risks that would be associated with breach of confidentiality.

No legal risks are expected.

e. Financial risks to the participants.

No financial risks are expected.

## 9. Benefits

a. Description of the probable benefits for the participant and for society.

The risks posed to individuals who participate are minimal. Potential indirect benefits include social and healthcare service referrals. Another potential benefit is that participants may experience the altruistic benefit of participating in a study that contributes to health of Latino communities.

All participants will be informed specifically of potential risks involved with the current protocol. Risks of participation will be minimized through the use of careful assessments and procedures designed to maintain confidentiality. Given that the overall level of risk associated with study participation is minimal, the risk/benefit ratio is weighed in favor of pursuing this research.

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**10. Payment and Remuneration**

- a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

In order to compensate participants for time and effort, they will be compensated appropriate to the current compensation rates for participation with similar approaches. Participants will receive \$25 for completing the survey.

**11. Costs**

- a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.

N/A

**12. Transfer of Materials: N/A**

Transfer of biospecimens from Johns Hopkins to another organization for research purposes and receipt of biospecimens from an outside organization for your research must adhere to JHU policies for material transfer (<https://ventures.jhu.edu/faculty-inventors/forms-policies/>) and biospecimen transfer ([https://hpo.johnshopkins.edu/enterprise/policies/176/39187/policy\\_39187.pdf?\\_=0.622324232879](https://hpo.johnshopkins.edu/enterprise/policies/176/39187/policy_39187.pdf?_=0.622324232879)).

**Please complete this section if your research involves transfer or receipt of biospecimens.**

- a. Will you **receive** biospecimens from an external entity for this research? [Yes/No].  
If “Yes”, please confirm you will secure an MTA/research agreement from the appropriate office (JHTV/ORA) prior to transfer.  
See: <https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/>.
- b. Will you **transfer** biospecimens to an external entity as part of this research? [Yes/No]  
If “Yes”, please address each of the following:
  - 1) Describe the nature of the research collaboration with the external entity and the rationale for the transfer. (Include an explanation of your intellectual contribution to the design of the research study, resulting data and sharing, and participation in the planned publications.)
  - 2) Please confirm you will secure an MTA through the appropriate office (JHTV or ORA) prior to transfer.  
(See: <https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/>.)
  - 3) If the biospecimens you intend to transfer were obtained through clinical or research procedures at Johns Hopkins and “Other” is selected in Item 4, Section 23, please submit the following items in that Section:
    - a. A pdf version of a completed JHTV Online “Material Transfer Agreement Request Form for Outbound Material” <https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/>

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[transfer/material-transfer-agreements/](#) **OR** a copy of the COEUS PD (Proposal Development Summary).

- b. A completed Biospecimen Transfer Information Sheet  
[https://www.hopkinsmedicine.org/institutional\\_review\\_board/forms/](https://www.hopkinsmedicine.org/institutional_review_board/forms/).
- c. A signed and dated “De-identified Human Subject Certification”  
[https://www.hopkinsmedicine.org/institutional\\_review\\_board/forms/](https://www.hopkinsmedicine.org/institutional_review_board/forms/)
- d. Approval documents from recipient site, if applicable.
- e. Copies of the consent forms associated with the IRB protocols under which the biospecimens were collected, with language appropriate to this transfer highlighted.
- f. The name of the specialist you are working with in ORA to complete a contract/MTA.

Please see the following website for more information about transferring human biospecimens to outside entities:

[https://www.hopkinsmedicine.org/institutional\\_review\\_board/news/announcement\\_transfer\\_human\\_biospecimens\\_outside\\_entities.html/](https://www.hopkinsmedicine.org/institutional_review_board/news/announcement_transfer_human_biospecimens_outside_entities.html/) .