

**CRISOL Contigo: a Multi-level Intervention to Reduce the Disproportionate Toll of COVID-19 Among Latino Communities in Philadelphia. (CRISOL Contigo)**

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Proposal:

1) **Protocol Title:** Cultivating Resilient and Strong Opinion Leaders (CRiSOL) Program

2) **IRB Review History:**

Considering that our initial exit interview was design to ask about a 1-year intervention focus on a different topic, we are submitting a more complete instrument that focuses on COVID-19. Finally, we are requesting to add a new member to our study.

Past modifications have been made to reflect COVID-19 recommendations. We requested a modification to our protocol to hold our biweekly intervention sessions via Zoom and to extend data collection efforts to on online or phone format in order to minimize spread of the virus. To reflect these changes we also requested changes to our dispersal of incentives, to allow for alternative modalities that do not require meeting face to face with participants. In June, we submitted a modification to expand the outreach in the community for 3 more months (until end of September 2020). We requested a modification to extend our project for a second year and submitted all necessary materials.

3) **Objectives:**

The purpose of this study is to implement an additional module related to COVID-19 to our pilot peer-driven intervention that seeks to address a cluster of health issues that have been shown to impact Latino immigrant communities. These health problems include Substance Abuse, Violence exposure, HIV/AIDS, and Mental Health (SAVAME). These conditions represent a syndemic because they act synergistically, and stem from multiple, common social and environmental determinants. The Cultivating Resilient and Strong Opinion Leaders (CRiSOL) intervention aims to reduce the impact of the SAVAME syndemic and COVID-19 among Latino immigrants in Philadelphia by integrating a community resilience and opinion leader framework.

The specific aims of the pilot study are:

1. To adapt and integrate two interventions previously implemented by our community partners in order to develop a new intervention to reduce the impact of the SAVAME syndemic among Latino immigrants in Philadelphia, with emphasis on changing social norms, promoting utilization of SAVAME-related health, behavioral, and social services, and promotion of individual and community resilience.
2. To recruit and train a small sample of peer leaders and implement the Creating Resilient and Strong Opinion Leaders (CRiSOL) pilot intervention in Philadelphia communities where Latino communities concentrate.
3. To test the pilot intervention using a comprehensive evaluation framework to generate feasibility, acceptability, and pilot efficacy data that will inform a future R01 application proposing an effectiveness trial of this intervention.
4. Include an additional 16-hour module related to COVID-19 to our previous implemented pilot.

#### **4) Background:**

Project CRiSOL will incorporate resilience training with an established peer-driven intervention framework in an effort to address the health disparities that exist among Latino immigrants. CRiSOL focuses on a set of four inter-related syndemic conditions among Latinos: substance abuse, HIV, domestic violence and mental health. During the second year, we will focus on COVID-19.

This project focuses on Latinos, the nation's largest racial/ethnic minority group in the U.S.<sup>2</sup> due to the mitigating social factors that they experience: 1 in 3 adults has not completed high school, 1 in 4 lives in poverty,<sup>15</sup> 1 in 4 is uninsured,<sup>16</sup> and half experience discrimination and prejudice.<sup>17</sup> These social disadvantages result in health disparities, including a disproportionate impact of HIV, substance abuse, mental health problems, violence; and most recently, COVID-19.

Latinos represent 17% of the U.S. population but they make 21% of new HIV infections and have a diagnosis rate 3 times that of non-Hispanic Whites (NHW).<sup>18</sup> Latinos are also diagnosed later<sup>19</sup> and have lower rates of viral suppression than their NHW counterparts.<sup>20</sup> The disparities extend to other STIs. For example, rates of chlamydia, gonorrhea, and syphilis are 1.8-2.2 times higher for Latinos compared to NHW.<sup>21</sup>

Alcohol and substance abuse levels among Latinos are comparable to or greater than in other groups, but there are notable disparities in access, quality of care, and adherence to substance treatment among Latinos, calling for evidence-based and culturally responsive strategies to minimize these disparities.<sup>22</sup>

About 28% of Latino men and 30% of Latinas will develop a psychiatric disorder over their lifetime.<sup>11</sup> Latinos have the second highest rate of severe depression, the highest rate of moderate depression,<sup>23</sup> and more signs of anxiety than other groups.<sup>24,25</sup> Yet, this group is less likely to seek mental health care and shows lower rates of anti-depressants or anxiety-reducing medication utilization compared to NHW.<sup>26</sup>

Latinos also experience a greater burden of violent victimization compared to NHW.<sup>27</sup> Although levels of intimate partner violence (IPV) do not differ much between Latinos and other groups, socio-economic conditions, cultural beliefs, and immigration-related factors perpetuate and exacerbate the impact of IPV among Latinas.<sup>28</sup>

This study focuses specifically on immigrants because migration is a social determinant of health.<sup>1</sup> About 48.7% of Latino adults in the U.S. were born in another country,<sup>2</sup> representing a particularly vulnerable population who faces additional disparaging barriers to health and health care, including poorer working conditions, acculturative stress, and discrimination.<sup>3,5,29</sup> For 9 million Latino immigrants,<sup>6</sup> undocumented status further limits access to services, education and work opportunities.

HIV, substance use, violence, and mental health have an even greater impact on Latino immigrants. Immigrants account for 43% of new HIV diagnoses in Latinos,<sup>30</sup> are at increased risk of delayed HIV diagnosis and late presentation to care, and have shorter survival compared

to non-immigrant Latinos.<sup>10</sup> Studies, including some by our own team, have shown high rates of STIs, sexual risk behavior, and substance abuse, among Latino immigrant samples<sup>31–33</sup> and indicated a negative impact of migration to the U.S. on these behaviors. Cumulative exposure to U.S. society and higher acculturation increase the risk for substance use<sup>34</sup> and psychiatric disorders.<sup>11</sup> Immigrant women experience higher rates of IPV<sup>35–38</sup> and are less likely to seek services than native populations.<sup>9</sup>

Changes in immigration policies and enforcement practices, possible undoing of Obamacare, as well as growing anti-immigration sentiments will likely exacerbate health disparities experienced by Latino immigrants over the next four years. President's Trump threat to defund Sanctuary Cities, like Philadelphia, can have profound effects on vulnerable communities and, especially, immigrant populations. The evolving socio-political climate is expected to translate into an increase in prevalence and less access to services,<sup>39</sup> especially for stigmatizing conditions and behaviors such as HIV/STIs, substance use, mental health, and violence victimization. Research to identify effective strategies for their prevention and treatment and to promote resilience among immigrant populations is timely and more relevant than ever.

Project CRiSOL focuses on a syndemic of health factors, instead of just one factor since the syndemics conceptual framework is gaining ground in public health and health care delivery.<sup>40</sup> Syndemics theory compels us to try to understand how different health problems “interact synergistically” within a community, identify risk and protective factors that connect them, and develop integrated interventions to simultaneously address these concomitant health problems and their shared social determinants.<sup>41</sup> As stated in the Lancet's Syndemic Series, a syndemics approach is a notable conceptual instrument in population health science<sup>42</sup> and can be used to tackle health inequities in a comprehensive and effective way.<sup>40</sup>

A syndemic model of substance use, HIV/AIDS, violence, and mental health (SAVAME) has been established among Latinos.<sup>14,43–45</sup> The adverse interaction of the SAVAME factors is well documented. Limited access to HIV treatment augments the physical and mental health impact and perpetuates transmission of HIV. Substance abuse increases the risk for HIV/AIDS,<sup>46</sup> poor mental health,<sup>47</sup> and violence victimization.<sup>48–50</sup> Mental health conditions can lead to drug addiction,<sup>51</sup> violence,<sup>52</sup> and HIV risk behavior.<sup>53</sup> IPV is a risk factor for HIV infection and a cause of stress and trauma.<sup>54</sup> However, despite evidence of these synergistic interactions, these problems continue to be tackled separately.

Evidence on effective strategies to curb the SAVAME syndemic afflicting Latino immigrants is sorely needed. Peer- driven interventions have been found to increase access to health care and contribute to reduce health disparities among hard-to-reach, marginalized communities.<sup>55–57</sup> A particularly successful peer-driven approach is the Popular Opinion Leader (POL) model. Based on the Diffusion of Innovation theory,<sup>58</sup> POL programs recruit and train influential community members to serve as early adopters of new behavioral norms (e.g. risk reduction practices, utilization of prevention and treatment services, etc.), helping disseminate these new norms among community members in their social networks.<sup>59,60</sup> POL approaches have been applied with success to address HIV risk,<sup>60</sup> but without enough attention to the syndemic relation with substance use, poor mental health, and violence victimization.<sup>61,62</sup>

A community resilience framework offers an innovative approach to address the SAVAME syndemic among Latinos. Resilience theory is a strengths-based approach to enable individuals and communities to successfully overcome adversity and trauma.<sup>63-65</sup> Community resilience can be fostered by engaging and empowering members of disadvantaged and underrepresented communities in health promotive activities and establishing formal and informal ties between these individuals and the available assets and resources in the community.<sup>64,66,67</sup> Identifying, engaging, and empowering influential Latino community members to serve as agents of change within their own social networks could increase the capacity of this community to respond to the SAVAME syndemic in more effective and sustainable ways.

The Philadelphia AIDS Consortium (TPAC) has experience using a POL model for HIV prevention and has begun to offer Resilience Training to providers and community members in Philadelphia. In this pilot study, we have adapted TPAC's existing POL program<sup>68</sup> to target the four SAVAME syndemic factors, not just HIV risk, in the Latino immigrant community. Elements of other evidence-based Latino interventions have been incorporated to address the mental health, domestic violence and substance use components. In addition to this new syndemic approach, the POL program will be enhanced with elements from TPAC's Resilience Training program. This enhancement recognizes that peers often face the same challenging circumstances as the individuals they are trying to help and these challenges reduce their ability to serve as influential change agents.<sup>69,70</sup> The Resilience Training will empower POLs to more aptly overcome adversity, so they can also better serve their communities. Resilience training will bolster the impact and sustainability of the POL program. To our knowledge, no intervention has incorporated syndemics, POL, and resilience theory to address the SAVAME syndemic in Latinos.

This study has two components that will help fill needed research gaps. The first component will be the adapted POL training program, where Latino immigrant leaders (hereafter referred to as POLs) will be trained and equipped with various skills and knowledge to help peers in their communities. Throughout this research proposal, this component of the research study will be designated as: "POL program" or "POL Training Program".

Once POLs are trained, they will be surveying their peers in the community (hereafter referred to as "community contacts") about their experience with the POL (e.g. satisfaction, intentions to follow-through with referrals). Community contacts are individuals within the POLs social network who are potentially at risk for or affected by the SAVAME factors. POLs will also offer community contacts the opportunity to take a survey about their experiences with the SAVAME syndemic. This survey hopes to gather preliminary data about the extent to which SAVAME conditions impact Latino immigrants in Philadelphia. Any section of this IRB proposal discussing the community contacts survey component of the research study will be designated "Community Contacts". These layers of participation are standard in peer-driven research projects, where peers have often been trained to serve as intervention delivery agents and to collect data from community members<sup>71-73</sup>. Peer researchers have an important role community-based participatory approaches to researcher.

## **5) Inclusion and Exclusion Criteria:**

### Popular Opinion Leaders (POLs)

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This is a community-academic collaborative study. Our community partners will select POLs through their own contacts in the community, aided by intervention advertisement flyers. Applying the POL model, community partners will identify men and women who are most popular, well-liked, and trusted by others in the Latino immigrant community. Specific inclusion criteria are listed below:

- Over 18 years of age
- Bilingual in English and Spanish
- Member of Latino immigrant community (self-identified)
- Experience or connection with the SAVAME factors (e.g. they or someone close to them have been affected at some point by one or more of the syndemic factors).
- Self-describes as "people's person" and comfortable talking to others
- A significant social network in Philadelphia (self-report)
- Perceived as trustworthy and influential (by self and by community partners)
- Highly motivated to serve as agents of change in their community (self-report)
- Have time for training and project-related activities (self-report)
- Plans to stay in Philly for the foreseeable future (self-report)

Our team will strive to recruit a diverse group of POLs, in terms of gender, country of origin, sexual orientation, and area of residence, so their networks can reach a large and diverse share of the Latino immigrant population in Philadelphia.

Eligibility to be a POL will be determined through interviews with co-investigators and community partners. Final selection of POLs will be at the discretion of co-investigators and community partners after the interview process.

For the second year, POLs that participated during the first year will be invited to participate. Additionally, we will recruit new leaders using flyers.

Community contacts:

As interventionists and data collectors, POLs will interact (i.e. face to face, social media, by phone) with community contacts within their own social networks during POL outreach. They will document the reach of the intervention using iPads provided by our project and equipped with the Qualtrics survey software offline application or using a link on their phones.

Every time they interact with a community contact as part of the CRiSOL intervention, they will fill out a brief questionnaire (i.e. "POL Activity Log Survey"). Post interaction with POL, POLs will go through a brief verbal consent process and ask community members to complete a brief anonymous 2-minute "Satisfaction Survey.", followed by basic demographic characteristics to understand the population they are reaching. For a clearer description of the process, see the study timeline in the next section. If the contact was not made face to face, the POL will ask the community member to complete the survey through an online anonymous survey.

Inclusion criteria for the community interaction is as follows:

- 18 or older

- Bilingual in English or Spanish
- The POL had a conversation with them or provided services to them as part of the CRiSOL intervention.

We will use a shortened version of the consent form considering the information to be collected is not sensitive and consisting only of satisfaction items and demographics. Also, please, note that the surveys will not contain any contact information.

After completion of this survey, the POL will invite the community member to participate in a more in-depth 20-minute survey that will be managed by our staff. If the participant accepts, the POL will collect a phone/email so our staff can send the link for the survey. Additionally, participants will be invited to complete a follow-up survey 3 months after the first survey.

## **6) Study Timelines**

We anticipate that it will take approximately one month to enroll POLs for the CRiSOL training. During the enrollment period, POLs will complete baseline interviews that will take approximately 45 minutes. The CRiSOL training will consist of 40 hours, delivered in 4-hour training sessions at times that are convenient for the group of POLs and the research team. The initial training will be followed by 16 biweekly 3-hour reinforcement/booster sessions.

We anticipate that the CRiSOL intervention implementation will take place over a 8-month period. POLs will commit to complete and document interactions with at least 5 community contacts over each 2-week period. Each community contact will be asked to complete a brief two-minute anonymous “Satisfaction Survey” based on the interaction with the POL.

We anticipate that it will take approximately four months to compile, clean, complete primary data analysis and prepare a manuscript and/or final report.

For the second year, we will invite the same POLs to participate. The COVID-19 training will consist of 16 hours, delivered in 4-hour training sessions at times that are convenient for the group of POLs and the research team. The training will be followed by 18 bi-monthly 2-hour booster sessions.

Please refer to the following study timeline:

FIRST Year timeline:

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[illegible]

## SECOND Year – Extension

## Timeline

[illegible]



## **7) Study Endpoints**

The primary endpoint of this study is to be able to assess the feasibility, acceptability, and efficacy of a peer-driven intervention to address the factors that contribute to this syndemic, increase access to SAVAME and COVID-19 prevention and treatment services, and reduce the prevalence and impact of the syndemic conditions and COVID-19 on the Latino immigrant community in Philadelphia.

## **8) Procedures or Methods Involved**

### POLs:

Individuals must provide informed written consent to participate in the POL training. The training will cover contextual, etiologic and practical knowledge related to SAVAME syndemic and COVID-19 and its impact on the community; knowledge of and navigation through available SAVAME services; effective communication and messaging skills; and culturally appropriate screening, counseling, and referral/navigation techniques. Training will also cover resilience competencies (e.g. self-awareness, self-regulation, optimism, mental agility, strengths of character, and connection). POLs will be formally connected with service organizations via informative panel sessions with local service providers to facilitate referrals to these services. Finally, CRiSOL peers will be trained in rigorous and ethical data collection and documentation of activities; and professionalism and leadership skills. The training will use instruction, modeling, and extensive role play exercises to promote skills and confidence. In order to encourage attendance to the training program, POL's will receive transportation tokens for ten in-person training sessions at TPAC (112 N Broad St, Philadelphia, PA 19102). We foresee a scenario in which some POLs might have to miss a training session, and we would like to have video recordings of the training sessions available to them to stay on track with the training to avoid any potential risk of loss of confidentiality, these videos will be edited by our team to remove any information that the participants might share, or any discussions unrelated to the training content.

At the beginning and end of each training session, subjects will complete a questionnaire to assess pre/post short term changes in SAVAME-related knowledge, attitudes, counseling skills, self-efficacy and behavioral intentions to influence and support others, as well as their individual resilience. These questionnaires will cover knowledge, attitudes, self-efficacy, resilience, and behavioral intentions to practice the skills covered during each session, while in the initial training phase (first 10 sessions). All of the questionnaires will be completed using iPads provided by the project. For the second year, the pre/post questionnaire will be about COVID-19 related knowledge, skills, and self-efficacy.

After 1 month of the implementation period (Community experience phase), the research team will conduct a semi-structured interview to gather opinions and overall satisfaction with the training, suggestions for amendments to the training in the future and their experience during the first month of community outreach. At the end of the 8-month implementation period (community experience phase), the research team will conduct semi-structured qualitative interviews with POLs, regardless of their continuation or level of activity. These interviews will

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be conducted by trained project staff at TPAC offices. Questions for the exit interview will focus on the self-reported impact the training and application of CRISOL program had on POLs, including their assessment of the level, relevance, and quality of knowledge and skills acquired; impact on self-confidence, resilience, social capital, their role in the community, and future professional and personal plans. Interview guides will also cover challenges to serving as a POL, barriers and facilitators for their role, suggestions for ongoing support system, and ideas to maximize the impact of CRISOL on the community. This information will guide future improvements of the intervention.

POLs will document their activity in the community on the “POL Activity Log Survey” using iPads furnished with an offline Qualtrics® survey. POLs will log every interaction with community contacts and indicate the date, time, and place of the contact. POLs will also document their response to the issues discussed with the community contact which may include modeling of positive social norms, delivery of risk/harm reduction counseling, communication of health messages, linkage to resources, and navigation services to reduce SAVAME risk and impact. Collectively, we expect POLs will reach and register approximately 720 community contacts.

Project staff will also hold 16 bi-weekly recurring meetings (i.e. in person or via Zoom) with POLs after the training during the community contacts portion of the research study. Project staff will assess any additional support they can provide to POLs and track progress on the community contacts research. For the purposes of the intervention and to recruit individuals interested in being POLs and to increase awareness among community members about the CRISOL project, the project team will be creating a CRiSOL Facebook, and Instagram accounts. This strategy has become a standard in today’s community-based projects and an effective way to reach minority populations. For example, Omar Martinez from Temple University, a member of our research team, works with Latino populations on MSM issues using social media platforms (Twitter, Facebook, and Instagram) without any reported adverse events thus far. Creation of CRISOL social media accounts would also increase the perception of cohesiveness between the Latino-serving work that both Drexel and Temple Universities are engaging with. Recruitment flyers and photo updates of the POL intervention (uploaded after receiving consent from individuals in the photos) will be posted on social media accounts.

For the second year, after completion of first year intervention, POLs will be invited to participate in a second-year intervention. Those that accept to continue will undergo a COVID-19 16-hour training. Additionally, we will recruit new leaders to the project using a flyer. After which, they will continue with the community outreach phase for 9 months. POLs will document their activity in the community of this new phase on the “COVID Activity Log Survey”. It is expected that each POL will connect with a minimum of 10 contacts each month. During the community outreach phase project staff will also hold 18 bi-weekly meeting (in person or via zoom) with the POLs.

Community contacts:

Post interaction with POLs, community members will complete a brief anonymous “Satisfaction Survey” based on their interaction with the POL, in addition to basic sociodemographic

characteristics. Community members will be provided with the informed consent script and must agree to participate before beginning the survey. The CRiSOL survey would be self-administered when the POLs and community contacts meet face-to-face, or administered by the POLs when interactions are made via phone or other media. The latter situation will be the case when social distancing measures are in place due to the coronavirus. The survey relies on Qualtrics®.

Note that by closing the survey, the answers of the individual cannot be accessed anymore except by the research team and no names or identifying information is included in the survey. A small incentive (i.e. a tote bag with the logo of the project) will be given to participants for their time when interactions are done face to face. This will not be possible when interactions are not face to face, such as during the coronavirus crisis.

For this second year, the study will be similar. Community members will complete an anonymous brief “satisfaction survey” after giving verbal consent (use of short consent version). Additionally, for this second year we are adding a new survey. POLs will invite community members to participate and collect phone numbers of the ones that agree. The research team will contact the community members that expressed interest, provide with a copy of the verbal consent and provide a link for them to take the survey. This survey will not collect any personal data. 300 community contacts will be invited to complete a follow-up survey 3 months after the completion of the first survey. The personal information needed to contact participants (i.e. phone number and first name) will be stored in a password-protected document.

Program Facilitators:

After the training the research team will conduct a semi-structured interview with the facilitators to gather opinions and overall satisfaction with the training and suggestions for amendments to the training in future iterations. Due to COVID-19, interviews will be conducted over phone or via Zoom.

## **9) Data Banking**

All data will be retained for at least three years after the completion of the research. Only individuals who are members of the research team and have been approved by the IRB will be allowed to access the data.

## **10) Data Management**

Only individuals who have been approved by the IRB will be allowed to access this data. All data files will be encrypted, and password protected with passwords known only to the principle investigator, co-investigators, and other authorized members of the research team. Additionally, the CRiSOL team has obtained a Certificate of Confidentiality from the NIH to protect program participants in this study. All digitized records will only be accessible from password-protected computers. Information containing participant information will be stored in password-protected documents, and participant identifiers will be used in place of names. All data recorded on paper will be kept in a locked drawer in a project office. The researcher who collected the paper

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records will be responsible for transporting the data in a closed backpack or sealed folder from the intervention site to the project office. No paper records will include full participant name, sensitive information, or survey data. All other data will be retained for at least three years after the completion of the study except for contact information for community contacts.

POL:

Three different types of data will be collected from individuals participating in the POL training program.

Program records, training attendance logs, and observation checklists will be used to record the number and basic sociodemographic profile of POLs recruited, attendance to training sessions, and fidelity of each training session delivered relative to the training curriculum. These records will be primarily kept on paper and scanned or input into a password protected computer database and the team's password protected and encrypted Drexel One-Drive cloud account as needed.

Pre- and post-training questionnaires and weekly practice logs. POLs will complete questionnaires before and after each training session to assess pre/post short-term changes in SAVAME-related knowledge, attitudes, counseling skills, self-efficacy and behavioral intentions to influence and support others, as well as their individual resilience. These questionnaires will cover knowledge, attitudes, self-efficacy, resilience, and behavioral intentions to practice the skills covered during each session. These questionnaires will be completed using the Qualtrics Offline App on project's iPads. While in the initial training phase (first 10 sessions), POLs will also be required to complete weekly paper-and-pencil practice logs detailing their practice of the skills covered during previous training sessions.

For quantitative data, data collected through program logs, observation checklists, pre/post training questionnaires, activity logs and surveys will be entered into datasets (or downloaded from iPads/Qualtrics platform in the case of Qualtrics-based questionnaires or surveys). Process (reach, adoption, implementation) data will be analyzed using descriptive statistics (e.g. means, standard deviations, percents, frequencies, etc.). Given the small sample size (N=10), changes in POL outcomes (e.g. knowledge, behavioral intentions, etc.) will be determined using non-parametric tests for paired data: McNemar's test for binary outcomes and Wilcoxon's Signed Ranks Test for ordinal or interval variables. Analysis will be performed using IBM® SPSS® 22.0 and Stata 14.

The training and experience in the field as a POL is potentially transformative for POLs. At the end of the first month after the completion we will conduct semi-structured qualitative interviews with POLs. After the end of the first-year intervention leaders will be invited to participate in a second-year intervention, an exit interview will be conducted for those that do not wish to continue. For those that accept, the interview will be conducted at the end of the second-year intervention. These interviews will be conducted by trained project staff at TPAC offices. Questions will focus on the self-reported impact the training and application of CRISOL program had on POLs, including their assessment of the level, relevance, and quality of knowledge and skills acquired; impact on self-confidence, resilience, social capital, their role in

the community, and future professional and personal plans. Interview guides will also cover overall satisfaction with the training, challenges to serving as a POL, barriers and facilitators for their role, suggestions for amendments to the training and ongoing support system, and ideas to maximize the impact of CRISOL on the community. This information will guide future improvements of the intervention.

Qualitative interviews with POLs will be audio recorded and transcribed by project staff or by a HIPAA-compliant transcription service (e.g. Transcribeme, Inc.). When outsourcing the transcription work, our team will make sure the audio files are anonymized before sharing them with the transcription services. Transcriptions of the audio files will be coded and analyzed by researchers using thematic analysis and grounded theory, using NVIVO software. Audio files will be destroyed once the information is transcribed. A codebook with a priori codes and emergent themes will be developed after reading a subsample of transcripts. Codes will be subsequently revised and refined. Coding discrepancies and errors will be reconciled by consensus. Emerging themes and the coding/analysis process will be described in a final report.

NVIVO is a password-protected online software, and no POL identifiers will be used when uploading this information for analysis.

For this second year, data collection will be similar as first year. We are updating the pre/post questionnaire to reflect the COVID-19 training. At the end, of the second-year intervention a qualitative interview will be conducted with those that finish the intervention.

#### Community contacts:

As described above, after graduation, POLs will document their activity in the community using iPads furnished with an offline Qualtrics® survey. POLs will log every community contact they complete and indicate the date, time, and place of the contact (“POL Activity Log Survey”). For each community contact, POLs will document their community contacts’ responses to the issues identified, which may include modeling of positive social norms, delivery of risk/harm reduction counseling, communication of health messages, linkage to resources, and navigation services to reduce SAVAME risk and impact. POLs will offer the community contact to take a satisfaction survey. The first survey (“Satisfaction Survey”) can be self-administered by the community member and is designed to collect data on basic sociodemographic characteristics (e.g. age, gender, sexual orientation, race/ethnicity, etc.) and their satisfaction with the services received from the POL.

Collectively, we expect POLs will reach and register approximately 720 community contacts. These data will serve to establish the level of reach, implementation (feasibility), and maintenance of the intervention in the community and provide important community-level baseline data to describe the population reached by the POLs.

These quantitative data will be analyzed as follows: Parametric (one-way repeated measures ANOVA) or non-parametric tests (Friedman’s test, general estimated equations), depending on

the level of measurement and observed distribution of the information. Analysis will be performed using IBM® SPSS® 22.0 and Stata 14.

All surveys offered as part of data collection on the community contact section of this protocol will be collected with and stored in Qualtrics®.

For the second year, we expect to follow same procedures as prior year. Additionally, we will be inviting community members to participate in an additional survey that measures risk behaviors and protective factors for SAVAME and COVID-19, as well as sociodemographic characteristics. After 3 months, those that expressed interest and gave consent will be contacted to complete a follow-up survey. These surveys will be collected and stored using Qualtrics®.

#### Program Facilitators:

At the end of the training period we will conduct a semi-structured interview with the facilitators to gather opinions and overall satisfaction with the training deliver, barriers perceived and suggestions for amendments to the training. These interviews will be conducted by trained project staff in a location agreed by facilitators. Due to COVID-19, the interviews will be conducted over phone or via Zoom.

Qualitative interviews with facilitators will be audio recorded and transcribed by project staff or a HIPAA-compliant transcription service. Transcriptions of the audio files will be coded and analyzed by researchers using thematic analysis and grounded theory, using NVIVO software. Audio files will be destroyed once the information is transcribed. A codebook with a priori codes and emergent themes will be developed after reading a subsample of transcripts. Codes will be subsequently revised and refined. Coding discrepancies and errors will be reconciled by consensus. Emerging themes and the coding/analysis process will be described in a final report.

### **11) Provisions to Monitor the Data to Ensure the Safety of Subjects**

As participation in either branch of this study (POL training or community contacts) involves minimal risk to the subjects, this section is not applicable. (N/A)

### **12) Withdrawal of Subjects**

During the consent processes, potential participants will be informed that the alternative to study participation is not to participate. If participants choose to withdraw, all data collection will stop immediately.

### **13) Risks to Subjects**

A small reasonable risk to participants is their loss of confidentiality. All qualitative interviews for both POLs and community contacts will be conducted in a private space, inside of a large office building in Center City, Philadelphia (TPAC). Risks to privacy will be minimized through staff ethics training, layered data security and by restricting access of sensitive information to

staff members who have a specific need for the information. Risks will also be minimized through requesting an NIH Certificate of Confidentiality.

Though the semi-structured interview guide used to interview POLs after their experience with the program will focus on their experience with the training and with the work in the community, it is possible that POLs may discuss their own personal experiences or those of others. With this possibility, comes the risk that some information may cause an emotional reaction. However, participants will be made aware that they can refuse participation at any time or reschedule the interview. Refusing to participate or rescheduling will not be held against participants. They will also be told to not use names or specific identifying information during the interview, as the interview will be audio recorded.

As part of the CRiSOL training, all POLs will be trained in the ethical treatment of study subjects and subject data with special emphasis in maintaining confidentiality. POLs will offer community contacts the opportunity to answer a sets of questions about their experiences and satisfaction with their encounter with the POL and basic demographic characteristics.

For community contacts, there is no potential risk since the information ask would not be sensitive. But we will minimize the potential for psychological discomfort by informing the participants that they are not required to participate in the study, that they should only share information they feel comfortable sharing, they can refuse to answer any questions or withdraw from the study completely, and that there is no penalty for not participating. Participants will also be informed that their personal information will be de-identified. The POLs who have had the contact with the community contact will not have access to the survey results and will not be involved in data analysis.

The risk of loss of confidentiality for community contacts is very low given the procedures we are using, such as collecting and storing respondent contact information in a different location from survey data and using unique identifiers. All data will be stored in password-encrypted files, and access will only be given to trained, authorized personnel.

#### **14) Potential Benefits to Subjects**

##### POLs

POLs will have the opportunity to learn about the health issues that impact their community and gain multiple skills. The CRiSOL training program expands opportunities to learn valuable information from CRiSOL trainers and services providers in Philadelphia. This training also provides the opportunity to gain leadership skills, including training in motivational interviewing, communication skills and making and scheduling appointments. Additionally, training provides POLs the opportunity to play an active role in addressing the SAVAME syndemic and COVID-19 among Latino immigrants in Philadelphia, which may lead to personal satisfaction and a better sense of connection to their community. This study hopes to provide information to help characterize and address the SAVAME syndemic among Latino immigrants. Since POLs will be drawn from the Latino community in Philadelphia, this knowledge may benefit POLs as well.



The CRiSOL team will be applying to the National Association of Social Workers to qualify the training for an official certificate. This certificate would be able to be used as continuing education credits for POLs if they are Licensed Master Social Workers (LMSWs). This nationally recognized training certificate could be used on POL resumes to improve their job prospects.

To incentivize their participation, POLs will also be offered a \$50 gift card for every two-week period that they remain active in the program after graduating from the POL training program. Remaining active means attending meetings every two weeks, being available for a phone check-in during the week that no group meetings are scheduled. Due to COVID-19, incentives will be dispersed online or through mail, based on feasibility and convenience for the leaders.

For the second year extension, POLs will be offered \$300 gift card for completion of the training phase, and a \$100 gift card every two-week period that they remain active in the program. Additionally, each month participants will receive a \$50 card to cover travel expenses related to their participation in the program. At the of the second year, POLs will receive a \$25 gift card for the completion of the exit interview.

#### Community contacts:

The satisfaction community survey will be offered to all community members who the POLs interact with. Community contacts will also benefit from the informal support and resource referrals that POLs offer.

To incentivize their participation, community contacts will be offered a small token of appreciation for their participation in the satisfaction survey. This token will be an item branded with the CRiSOL and/or Drexel logos, such as a tote bag.

The community contacts that agree to participate in the additional surveys (i.e. base and follow up) will receive a \$25 e-gift card.

### **15) Vulnerable Populations**

Participation in both the POL training program and the community survey will be 18 years or older and identify as Hispanic or Latino. No prisoners or children will participate in this study.

Community contacts who are potentially at risk for or affected by the SAVAME factors, especially violence or HIV/AIDS may be considering vulnerable due to the stigma and sensitive nature associated with this community in the United States. POLs will be trained extensively to understand and address factors leading to vulnerability in specific situations, including situations that arise when working with marginalized groups. When working with particularly vulnerable



groups, it is important to take all ethical considerations into account, to further protect these individuals.

Though this research will not inquire about the immigration status of any individual, there is a chance that POLs may divulge their immigration status in qualitative interviews. To protect these individuals, we will request a certificate of confidentiality.

For the community contact survey, no information about immigration status or contact information will be requested.

The researchers have determined that the project contributes to further knowledge expansion and literature for the target population and all required precautions will be done to confirm ethical execution of the project.

## **16) Multi-Site Research**

This is not a multi-site research study, and as such, this section is not applicable. (N/A)

## **17) Community-Based Participatory Research**

Our community-academic partnership includes members from Drexel University, TPAC, and Temple University. It also includes a licensed clinical psychologist who is a trusted member of the Latino immigrant community in Philadelphia and has a history of collaboration with the PI of this project and with TPAC. TPAC is a non-profit organization that provides the following services:

- direct health and social services
- referrals to racial/ethnic minority and low-income communities
- leadership and certification training
- capacity building
- technical assistance.

TPAC has two locations: one in Center City, catering mostly to South Philadelphia residents; and one in North East Philadelphia, serving residents of North Philadelphia neighborhoods. Our community-academic team is multidisciplinary and has extensive experience in survey methods (Martinez-Donate); syndemics (Martinez); mixed methods and intervention design (Martinez-Donate, Martinez); network diffusion measures (Hassrick), and POL and resilience programming (Yoshiaki, Perez). The overall project will be guided by the community participatory research (CBPR) principles of co-learning, capacity building, benefits to all partners, and long-term commitment to improve the health and well-being of the community.

## **18) Sharing of Results with Subjects**

Results of this study will be shared with the POLs as well as members of Latino-serving organizations during community meetings (date and time TBD) held at either TPAC, WOAR, or

Nesbitt Hall (Drexel Dornsife School of Public Health building). Efforts will be made to prioritize any interested subjects' setting preferences, including date and time of day. While the meetings will be open to anyone from the community, we do not anticipate to be able to share the results with the survey respondents, as contact information will not be collected.

## 19) Setting

Recruitment, interviews, and training sessions with POLs will take place at TPAC, located at 112 N Broad Street, Philadelphia, PA 19102.

Interactions between POLs and community contacts have no pre-determined setting, and will take place in settings that are most convenient for both the community contact and POL, and will be mutually decided by the community contact and POL. Due to COVID-19, these contacts might be held over the phone or online to minimize spread of disease. Efforts will be made to prioritize the community contact's setting preferences, including date and day of time. Recruitment with community contacts will take place at TPAC or a location that the respondent feels most comfortable and allows for privacy. The satisfaction survey will be delivered in this setting. POL's will be given training to ensure that locations chosen protect respondent's confidentiality and maximize respondent's comfort. Examples of locations are private meeting rooms at TPAC, private meeting rooms at Drexel University, etc.

## 20) Resources Available

We recruited 9 POLs and plan to recruit 720 community contacts. These numbers are based on several factors: a) Resources (funds and personnel) and time available to the project; 2) Previous experience conducting research with Latino populations by the study team; 3) Size of the Latino population in Philadelphia; and 4) Discussions with our community partners.

We expect that at least 8 POLs will continue during the second year. Additionally we plan to recruit 720 community contacts, from which 300 will filled the additional surveys.

Our team has the following **people-based resources** available to us to conduct the study:

- **Ana Martinez-Donate, PhD** (*myself*): I am an associate professor in the Department of Community Health and Prevention at the Drexel University Dornsife School of Public Health. My academic training, cultural background, and research experience have prepared me well to direct this study. I have a PhD in health psychology and my postdoctoral work focused on HIV prevention and tobacco control research with Latino populations. I am a fully bilingual Latina. During the last 11 years, I have been serving as PI for NIH-funded research aimed at estimating the risk for HIV infection, identifying risk determinants, and examining health care access among Mexican migrants and immigrants. In recognition of the novelty and potential of this work, I received a Presidential Early Career Award for Scientists and Engineers in 2009. I have served as principal investigator and co-investigator for a number of research studies examining

determinants of health behaviors and effective strategies for disease prevention and health promotion at the population level. I have extensive experience in the development and implementation of population-based phone, household, and intercept surveys on HIV risk and other health topics among Mexican migrants and immigrants in the U.S. and Mexico. I have conducted longitudinal research with Mexican adolescents in Tijuana, Mexico, and recent Latina immigrants in the U.S. I am also proficient in the use of qualitative methods. I have demonstrated my ability to partner with various academic and community-based agencies and conduct population health research in both domestic and international settings. I have been conducting research in Philadelphia for 3.5 years, and have close contacts at TPAC, Temple University, and other organizations in the area that work with Latino populations. I will be dedicating **15%** of my time to the CRiSOL program.

- **Omar Martinez:** Omar is currently an Assistant Professor (Tenure Track) at Temple University's School of Social Work and College of Public Health. Omar has research expertise in the correlates, prevalence, and prevention of substance use/disorders, mental illness, and HIV risk behaviors among underserved and vulnerable populations, including Latino men who have sex with men (MSM). Omar's work explores the impact of syndemic factors, including individual-level factors (e.g. substance use and mental health problems) and the larger social context (e.g. immigration status, immigration policies, laws, acculturation issues, language barriers, experiences of discrimination, and neighborhood residence) that affect overall health outcomes among Latino LGBT populations. Omar's experience includes developing and implementing programs and interventions to address health disparities affecting Latinos and other underserved populations; including HoMBReS, a best-evidence community-level HIV prevention intervention for self-identified heterosexual Latinos; and Connect 'n Unite, a couple-based behavioral HIV prevention intervention for substance using Black MSM; both interventions were funded through NIH. Omar is also the PI of a 4-year CDC funded randomized clinical trial study, Conectando Latinos en Pareja, a couple-based bio-behavioral HIV prevention intervention for Latino MSM. In addition, I have been involved in several grant foundation research projects including a recent study titled "STD Testing: Behavior & Barriers among Sexual & Gender Minority Youth" with Public Health Solutions, Inc. in New York City. For this proposed study, Omar will contribute with my expertise in HIV and Syndemic research among Latino populations, contributing to the design of the recruitment strategies and development of screening tools for the detection of SAVAME factors and theoretical determinants to be used by the peer leaders in the intervention. Omar will work with Dr. Martinez-Donate and the research team in the intervention design, facilitation of intervention health education trainings sessions, interpretation and application of the pilot study results for the design of a future effectiveness trial.
- **Elizabeth McGhee Hassrick:** Elizabeth is a sociologist with extensive expertise in studying social networks and their impact on organizational and individual outcomes. She has the theoretical and methodological training and the practical experience necessary to successfully serve as co-investigator for the proposed work. Elizabeth has served as (1) principal investigator for an NAEd/Spencer postdoctoral fellowship with the Duke University Network Analysis Center, investigating autism interventions in school and clinic contexts; and (2) co-investigator on an NIH R21, mapping the social

networks of ASD treatment providers across school, home and clinical settings. Both foundation grants supported data collection in school settings, investigating how school configuration shapes unequal outcomes for low income, minority students. Prior to her academic career, I taught for 10 years in high poverty urban and rural K-12 public schools, where I worked closely with district and school leadership to increase parent engagement among immigrant, African American, Hispanic and Native American families. Elizabeth has extensive research training and data collection experience in dynamic social network analysis and longitudinal social network analysis training. Elizabeth's deep expertise in organization-level assessment and social network analysis is more than qualifies her for this project. In particular, her previous training and current work have prepared her well to apply social network and diffusion of innovations theory to this study. Elizabeth will contribute to the development of ethnographic procedures to identify influential community leaders and the design of measures and procedures to assess the reach of the intervention in the Latino community.

- **Yoshiaki (Yoshi) Yamasaki:** Yoshi is a Mexican immigrant of Japanese descent with over 25 years of experience in the field of HIV/AIDS and human sexuality. His expertise has included developing and delivering training on HIV/AIDS prevention, testing, counseling, cultural sensitivity, and working with ethnic/racial and sexual minorities. He has developed and implemented HIV/AIDS programming for diverse populations in Philadelphia and for over 10 years he has served as a senior partner of the World Health Care Infrastructure d.b.a/TPAC, where he collaborated in global outreach initiatives for HIV prevention. Yoshi has experience and great interest in conditions that interact with HIV risk and infection among Latinos and have worked in collaboration with local CBOs, Mexican communities in the U.S. and in Mexico, and international organizations in Mexico for the eradication of sexual violence and HIV/AIDS. In addition, his educational background in social psychology has given me the foundations to approach the problem of HIV/AIDS from a socio, political, and cultural framework, therefore enabling him to take a holistic approach to program development and service delivery. In that regard, as Executive Director of TPAC, he is committed to developing and providing services that address the inter-related issues that contribute to, or result from, HIV infection and that prevent proper treatment and care for those affected. Finally, as a member of the board of directors for several Latino-serving CBOs in Philadelphia, he works with an extensive network of organizations and institutions that focus on a range of issues in the community, including sexual violence, substance use, reproductive care, and advocacy for immigrants. For the proposed pilot study, Yoshi will serve as the primary community partner and offer my expertise in HIV/AIDS and the interrelated or syndemic conditions present in the Latino immigrant community. As the community partner for this pilot study, Yoshi is ready to provide support with the intervention design and implementation, which will be adapted from our previous POL intervention and resilience training. He will also provide support with recruitment of community leaders, results interpretation, manuscript writing, and dissemination of study findings TPAC will also assist in developing a community resources list to be used by CRISOL peer leaders in their community work to connect peers to formal health and social community resources in Philadelphia.
- **Cristina Perez:** For over 25 years, Cristina has been working with Mexican and other Latin American immigrants in the U.S. Cristina's experience with the Latino community

includes development and provision of educational trainings on parenting skills, domestic violence, sexual assault, sexual harassment in the workplace, and individual and community resilience. These trainings are developed and tailored for a diverse population of community members as well as professionals. In addition, Cristina has extensive training and expertise in counseling and therapeutic services for victims of domestic violence, sexual assault, and trauma survivors. Cristina is currently the Director of Community Outreach for WOAR (Women Organized Against Rape) and has been there for 18 years. In this position, Cristina has developed and implemented numerous prevention programs, including a sexual harassment prevention program with Latino men who work in the restaurant industry in Philadelphia, using a peer-to-peer model. In 2015, Cristina was the award winner of a Robert Wood Johnson Foundation grant for the implementation of the Promoting Resilience Communities program at La Casa de Los Soles. This program provides training in the theory and application of Resilience to 1) education and mental health professionals and 2) all community members who want to acquire the skills and knowledge to be agents of change in their community. This training combines WOAR's well-established sexual assault preventive-education program with Resilience principles and methods, to promote physical, mental, and emotional health. The Individual Resilience and Community Resilience Training has the Latino immigrant community as its target and thus incorporates the different challenges immigrants confront during the different immigration phases to frame the challenges faced by this community and the tools to overcome them. Cristina's extensive experience working with the Latino community is well-suited for the proposed study, in which she will provide consulting services around intervention development, particularly for the incorporation of violence exposure, mental health, and the interconnections between these health areas and HIV/STDs, theory and concepts of individual and community resilience; co-facilitation of intervention training session and boosters; as well as assistance with the interpretation of findings and implications for scaling up the proposed pilot intervention in the future.

- **Jonas Ventimiglia** is a Data Analyst at the A.J. Drexel Autism Institute at Drexel University in the Life Course Outcomes Program. He has a BS in Psychology and is completing his MA in Quantitative Methods at the University of Maryland. His research background includes statistical and methodological work as well as a focus in child development. He will be applying his social network analysis skills as a data analyst under the supervision of Dr. Hassrick.

For this study, we also have the following student support:

- **Kristin Giordano:** Kristin is a Masters of Public Health candidate at the Drexel University Dornsife School of Public Health. She received her undergraduate degree in Hispanic Studies and Linguistics from the College of William & Mary, and has worked with communities in Nicaragua, Argentina and Chile. She previously worked for two years in the Colorado Springs Fire Department's Community Health & Prevention Division. She will be dedicating 15 hours per week to this project.
- **Jamile Tellez Lieberman, MPH DrPH(c):** Jamile is a doctoral candidate at the Drexel University Dornsife School of Public Health in the Department of Community Health & Prevention. She received her MPH degree at Drexel University and has significant

experience with working with the Latino and Latino immigrant communities in Philadelphia and other cities. Jamile is bilingual in English and Spanish. Jamile specializes in mixed-methods, community-based research with vulnerable or hidden populations. Her dissertation will focus on the health and well-being of children from Latino immigrant families who have been separated by deportation. Dr. Martinez-Donate is her doctoral advisor. Jamile will be dedicating 8-10 hours a week to the study.

- **Nishita Dsouza, MPH:** Nishi is a doctoral student the Drexel University Dornsife School of Public Health. She received her MPH degree at Washington University in St. Louis and has significant experience with community health and minority communities. She will be dedicating 20 hours a week to the study.
- **Maho Okumura:** Maho is a Master of Public Health candidate at the Drexel University Dornsife School of Public Health, majoring in Community Health and Prevention. Her research background prior to Drexel focuses on molecular biology, immunology, and microbiology, but she has worked with Dr. Martinez-Donate for a year on developing the CRiSOL project.
- **Emily Nolasco-Barrientos:** Emily is a Master of Public Health candidate at the Drexel University Dornsife School of Public Health. She is concentrating in Community Health and Prevention. She has experience working within community health as it pertains to minority populations. She received her B.S. in Biological Sciences with a minor in Women's Studies from the University of California, Irvine.
- **Nayrobi Mosquera:** Nayrobi is a Master of Public Health candidate with a concentration in Community Health and Prevention at Drexel University's, Dornsife School of Public Health. She received her BA degree in economics and a minor in public health from Wheaton College, MA. Her public health interests include Latino and immigrant health and has extensive research experience with racial and ethnic minority populations.
- **Claudia Zumaeta Castillo, MPH:** Claudia is a doctoral student at the the Drexel University Dornsife School of Public Health. She received her MPH degree at Drexel University and has experience with working with the Latino immigrant community in Philadelphia. Claudia is bilingual in English and Spanish.
- **Leah Bakely:** Leah is a Master of Public Health student at Drexel University. She is concentrating in Community Health and Prevention. Leah is bilingual in English and Spanish.
- **Sierra Cuellar:** Sierra is a Master of Public Health student at Drexel University with a concentration in Community Health and Prevention. Her Public Health interests include social determinants of health in vulnerable populations.
- **Gabrielle Connor:** Gabrielle is a Master of Public Health candidate at the Drexel University School of Public Health, majoring in Health Management and Policy. Her research interests include health policy, economics of health care, mental health and behavioral economics.

We have the following facilities available at our disposal:

- **Drexel University Dornsife School of Public Health – Nesbitt Hall:** The Dornsife School of Public Health is located at the heart of Drexel's main campus in the University City section of West Philadelphia in a newly renovated 78,000 square foot, seven-floor

dedicated building with easy access to a broad range of Drexel university resources, Philadelphia's Center City, and the 30th Street Station transportation hub. This location eases cross-disciplinary collaboration among University programs, allows Drexel students from other academic programs to more easily engage with the school's programming, and further enables the School to closely collaborate with communities in the surrounding neighborhoods. Nesbitt Hall was completely renovated and redesigned to meet the specific needs of a school of public health. The remodeled building includes: innovative research space, cutting edge classrooms, conference rooms with state-of-the-art communication capabilities, numerous open and flexible collaboration spaces, a student lounges, and other amenities. There are two large lecture halls on the first floor, available for School of Public Health use and the entire Drexel community. Several areas are designed to foster collaborative student work. Conference rooms in the School's space are used for administrative purposes, research meetings, committee meetings, doctoral defenses, and instructional classroom purposes. For the purposes of this study, meetings can be scheduled in Nesbitt Hall, and space will be used to store incentives.

POLs and participants will also use space at TPAC, public libraries, and other spaces deemed fit by both POLs and participants for meeting purposes.

Drexel University has medical and/or psychological resources available if necessary through the Drexel University School of Medicine and the Office of Counseling and Health Services. Mr. Yamasaki (TPAC) and Mrs. Perez have also identified themselves as available as psychological resources and have strong connections to any medical or psychological resources that participants might need to utilize.

All individuals that will be assisting with the study will be informed of study processes and resources through meetings. POLs will be made aware of resources through the CRiSOL training.

## **21) Prior Approvals**

Research team will request a Certificates of Confidentiality (CoC) to protect research data from forced disclosure in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Due to the sensitivity of data collected the CoC will assure the confidentiality of subjects' private information.

## **22) Recruitment Methods**

POLs will be recruited by our community partners from the community. Participants will receive informed consent information prior to the baseline survey. Participants of the POL training may withdraw from the study at any time with no adverse consequences.

### **23) Number of Subjects**

This study aims to recruit and train 10 POLs and 720 community contacts. And for the second year, aims to retain 8 POLs and recruit a total 720 community contacts.

### **24) Confidentiality**

Risks to privacy will be minimized through staff ethics training, layered data security and by restricting access of sensitive information to staff members who have a specific need for the information.

- Training: All study staff are trained in the ethical treatment of study subjects and subject data with special emphasis in maintaining confidentiality.
- Data Security: All data files will be encrypted, and password protected with passwords known only to the principle investigator, co-investigators, and graduate students.

#### Community contacts:

The data collected from community contacts will be **anonymous** if participants agree to take the “Satisfaction Survey”. Throughout the study, the privacy interest of community contacts will be protected, no contact information would be collected for participants. The database will be accessible by selected team members on an “need-to-know” basis and will remain in a password-protected and encrypted folder.

### **25) Provisions to Protect the Privacy Interests of Subjects**

During the consent process, participants will be given the option to not participate in the study and the option to withdraw at any point without having to be penalized.

The nature of the project is voluntary. Throughout the study, we will minimize any potential for discomfort by informing participants that they are not required to participate in the study, that they should only share information that they feel comfortable sharing, and that they can refuse to answer any questions or withdraw from the study at any point. In addition, all surveys will be administered through Qualtrics which is password protected, and will only be accessible from the primary account of the researcher who accesses it. Any data that is downloaded from Qualtrics will be stored on password protected computers and the Drexel OneDrive cloud.



## **26) Compensation for Research-Related Injury**

Not Applicable

## **27) Economic Burden to Subjects**

There is no economic burden unique to the study for the subjects. While CRiSOL is actively working to minimize the economic burden to participants, there may be some economic burden incurred through travel costs to the location of the trainings. CRiSOL is minimizing this cost to participants by hosting trainings at central locations and may consider looking into hosting some trainings in North and South Philadelphia, closer to participants. Economic costs associated with POL work with community contacts is minimal, since POLs will be interacting with the same people who they interact with in the course of their daily lives. The \$50 incentives provided for every two-week period that POLs remain active will help offset this burden.

## **28) Consent Process**

### POLs:

The research team is responsible for obtaining informed written consent from the participants of the POL training. Written information describing the research will be provided to the subject explaining that the study is voluntary, the purpose of the study, why they were chosen to participate, and what their participation entails. Participants will be provided with investigator contact information should they have any further questions. If the prospective subject agrees to participate, he or she will be asked to sign the consent form.

### Community contacts:

The verbal consent script will be provided to community contacts by POLs before the CRiSOL satisfaction survey. POLs will explain the study to the potential subject, providing all pertinent information and appropriate additional elements of consent disclosure. The research presents no more than minimal risk of harm to the subjects. Written information describing the research will be provided to the subject explaining that the study is voluntary, the purpose of the study, why they were chosen to participate, and what their participation entails. The consent process will take place the day of the interview. Participants will be provided with investigator contact information and will have ample time to ask questions. Participants will provide verbal consent before proceeding with the study.

Prospective participants may speak Spanish. For Spanish-speaking participants, POLs will go over the consent process with the participant and the consent form will be provided in Spanish. The consent process outlined will apply to Spanish-speaking participants as well.

### Facilitators:

Research team is responsible for obtaining verbal consent prior to the interview. Written information describing the research will be provided to the subject explaining that the study is

voluntary, the purpose of the study, why they were chosen to participate, and what their participation entails. Participants will be provided with investigator contact information should they have any further questions. If the prospective subject agrees to participate, he or she will provide verbal consent before the interview.

## **29) Process to Document Consent in Writing**

### POLs:

The informed consent process will be explained by either Dr. Ana Martinez-Donate, Jamile Tellez Lieberman, or Claudia Zumaeta Castillo in either English or Spanish. Written consent will be documented during the initial interview, prior to the POL training.

### Community contacts:

This study is requesting a waiver of written documentation consent, as the evaluation presents no more than minimal risk of harm to participants. The written script of the consent form provides all written information describing the study and will be provided to all participants. All study participants will provide verbal consent.

### Facilitator:

This study is requesting a waiver of written documentation consent, as the interview presents no more than minimal risk of harm to participants. The written script of the consent form provides all written information describing the study and will be provided to all participants. All study participants will provide verbal consent prior to the interview.

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