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Study Title: Hispanic Men Building Respect Education and Safety (Family Men) Substudy Under Center for Latino Research Opportunities (CLaRO)
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1) Protocol Title:
Hispanic Men Building Respect Education and Safety/ HoMBRES Manteniendo Respeto, Educacion y Seguridad *(HoMBRES* De Familia) - Substudy under Center for Latino Research Opportunities (CLaRO)

2) IRB Review History*
Previously approved by the UM IRB for NIH JIT purposes. The study is being conducted by FIU personnel under CLaRO. FIU has approved for UM to be the IRB of record.

3) Objectives*
The study described in this protocol is examining the efficacy of a culturally adapted group intervention program with fathers and their son dyads from a seasonal farm working community in South Florida. The goal of the HoMBRES de Familia project is to adapt and test the efficacy of an intervention that will be adopted, implemented, and sustained with Latino fathers who live or work in the farm industry, construction, sales, services, selfemployed, or any other work industry in the semi-rural areas or urban areas of MiamiDade County. The HoMBRES intervention will seek to reduce risk for the SAVA (Substance Abuse, Violence, AIDS) syndemic among this group of men and their adolescent sons.

The study aims of HoMBRES De Familia are:
1. Conduct a community assessment via qualitative data methods (in-depth interviews; focus groups) that will inform the adaptation of HoMBRES, an evidence-based intervention targeting the SAVA syndemic among adult and adolescent males in the Latino seasonal farmworker community;
2. Adapt, implement, and evaluate the preliminary efficacy of the adapted intervention through a randomized trial; and
3. In combination with the CLaRO Community Engagement and Dissemination Core, develop an effective dissemination plan that engages community members, partnering organizations, local service providers, and other stakeholders in disseminating study findings into a sustainable intervention that effectively reduces SAVA related health disparities among males in these communities.

4) Background*
Syndemic conditions refer to two or more intertwined endemic or epidemic health conditions that interact and impact the health of a population.[12] The syndemic framework promotes a deeper understanding of the relationships between co-morbid health conditions and how these health conditions may interact synergistically to negatively impact the health of affected communities. This framework emphasizes the underlying factors that link comorbid health and health disparity conditions together. When investigating the substance abuse, family violence, and HIV/AIDS (SAVA) syndemic among Latino men, it is essential to examine both the conditions themselves and the underlying individual (e.g., poverty, selfefficacy), interpersonal (e.g., family involvement, partner characteristics), cultural (e.g., machismo, gender norms, cultural stressors), and socio-environmental factors (policies, access to health care, structural stressors) that may serve as common risk and protective factors for these three conditions. Thus,

interventions that address the underlying multi-level factors linking the SAVA syndemic to effective programs can potentially and simultaneously reduce substance abuse, violence, and HIV risk behaviors among males in the Latino seasonal farmworker community.

An estimated four million farmworkers, mostly Latinos, live and work in rural areas in 42 of 50 states in the US.[13] Seasonal farmworkers are defined as individuals involved in field and orchard agriculture, packing and sorting procedures in food processing, horticultural specialties (including nursery operations, greenhouse activities, and crops grown under cover), and reforestation. Unlike migrant farmworkers, who leave their home to seek employment, seasonal farmworkers usually stay in their permanent place of residence and shift jobs depending on the season. Given South Florida's climate, most farmworkers in the area are seasonal and work in several areas of the agricultural industry in a given year.[14]

The life circumstances of seasonal farmworkers often place them at risk for substance abuse, family violence, and HIV/AIDS.[15,16,17] A confluence of socio-demographic, ecological, and behavioral factors contribute to the disproportionate rates of SAVA syndemic in this population. Farmworkers face social and structural barriers, including immigration status (fear of deportation), geographical isolation, language barriers, separation from extended families, hazardous working conditions, substandard living conditions, limited access to health services, poverty/economic stress, and ethnic/racial intolerance.[13,18] Many seasonal farmworkers report high levels of depression and anxiety, which exacerbate health-compromising behaviors.[15] Socio-cultural risk factors [e.g., acculturation and acculturation related stress, traditional gender roles (machismo), poor family functioning, and stigma] have been associated to increased risk of SAVA in this population.[19,16,20] Conversely, holding strong Latino cultural values such as *familismo* (i.e., strong family bond), *respeto* (respect for parents and elders), religiosity, and *caballerismo* (i.e., positive machismo; e.g., dignity, honor, man's role as provider) have been found to be protective against SAVA risk behaviors.[21,22]

Peer-advocate based interventions have been effective in decreasing health risk behaviors among Latino men.[2,3] Researchers attribute the success of these models to peeradvocates, who (a) reside in the community, (b) understand the communities' strengths and needs, (c) communicate in the language of the community, and (d) share cultural (e.g., identity, values, belief) similarities with the community to promote health outcomes within their communities.[23] Furthermore, intervention approaches that utilize existing community assets (e.g., peer-advocates) have been shown to remain effective after a research project or grant funding has ended—underscoring the impact and sustainability of these intervention models.[5] Given the efficacy of peer-advocate based models, such as HoMBReS and HoMBRes-2 among Latino males in rural areas, we propose to adapt these proven strategies within the local context of males. Specifically, in the proposed adapted intervention, HoMBRES de Familia, peer-advocates will target identified risk factors (i.e., stigma, machismo, stressors) and take advantage of key protective factors (i.e., familismo, respeto) associated with the SAVA syndemic in this population. For instance, peeradvocates will be trained to bolster positive, and reframe negative, socio-cultural expectations regarding masculinity, debunk SAVA-related myths, and increase knowledge and accessibility of available substance abuse, HIV/AIDS and other STI, and family violence services in the community.

Etiological studies among Latino adolescents have indicated that higher levels of positive family relationship processes, such as parental involvement, parent-youth communication, and family cohesion,[24] are associated with lower levels of substance use,[25,26] sexual risk behavior,[25] mental health,[27] and violent/aggressive behavior.[28] Intervention studies that enhance positive family relationship processes among Latino families simultaneously report decreases in these negative outcomes[29,30] However, most family-based prevention programs that target SAVA outcomes among Latino youth have a *significant* limitation: they are not tailored to gender-specific determinants of SAVA. Researchers have found that Latino adolescent boys who are socialized to adhere to machismo attitudes may be more inclined to engage in sexual risk and aggressive behaviors,[21,31] and the socialization of machismo may occur more commonly among immigrant families and families living in poverty.[32,33]

Family-based prevention programs that target SAVA outcomes among Latino adolescents and other ethnic minority youth may be more efficacious by increasing the father's involvement and strengthening father-son positive family relationship processes.[34,35] *Social Cognitive Learning Theory*[36] posits that fathers may serve as a more relatable *model* for adolescent sons. Few family-based prevention programs have focused on father-son dyads; however, there is evidence indicating that improving family functioning among ethnic minority father-son dyads may improve SAVA outcomes.[37] Research on father-son interventions have primarily focused on African American families;[34,37] there is a need for more studies investigating the Latino father-son context in this research area.

To date, no studies have examined the context of father-son relationship and communication and its impact on externalizing risk behaviors among youth among seasonal farmworkers. The scarce evidence in this area of research suggests (via qualitative in-depth interviews) that despite the challenges associated with their working conditions, LSFW fathers are motivated and seeking creative ways to express their roles as fathers.[38] Previous studies have found that, among Latino men, the cultural factors that protect them against the SAVA conditions—including higher levels of *respeto* (respect), *familismo* (familism), and *caballerismo* (positive aspects of machismo connected to chivalry and being family provider*)* — also make them more likely to be more involved with their children.[39,35,40] In contrast, acculturative stress and greater levels of acculturation have been found to negatively impact family relationships among farmworkers.[41,42, 43] The proposed HoMBRES de Familia will examine the unique intersections between behavioral, structural, and cultural circumstances experienced by seasonal farmworkers as a context of father involvement and leverage the LSFW fathers' interest in improving communications with their sons to reduce the prevalence of the SAVA syndemic among adult Latino males and enhance parenting skills that will ultimately lead to preventing these conditions in future generations.

Taking in consideration the US Department of agriculture's study from November 2018 reporting the shortage of farmers and plant growers in the US (Zong, Btalova, & Burrows, 2019; Krogstad, Passel & Cohn, 2019), the current study will recruit Latino males who live in the urban areas of Miami Dade, semi-rural areas of Homestead, Naranja and Florida City or work in the farm industry, sales, construction, truck industry, landscaping, self-employment or other work industry will be included in the study.

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5) Inclusion and Exclusion Criteria*

Latino fathers and father figures with 11-17 adolescent sons who live in or work in the farm communities, farm industry, construction, sales, services, self-employed, or any other work industry in the urban and semi-rural areas of Miami Dade County. We will be recruiting the sample, in part, through community-based agencies serving the Latino community in those areas.

Aim 1 –Participants in the Community Assessment will be recruited from the community using word of mouth, fliers, and outreach in the community. Focus groups will be facilitated with adult men, adolescents (13-17 years old), and service providers and community leaders, from the community. Criteria for participating in the focus groups are: 1) being a farm worker (or adolescent child of a farm worker) or living in a farm working community or working with the farm working community or being a leader within the community. 2) Speaking and Understanding English or Spanish

Aim 2 - In order to participate in the randomized clinical trial (RCT) intervention - Adult father and son (11-17 years old) dyads, living or working in the farm industry, sales, construction, truck industry, landscaping, self -employment or other work industry or living in the urban areas or semi-rural areas of Miami-Dade such as Homestead, Naranja and Florida City will be eligible to participate in the Research Project.

Prisoners are excluded. Inclusion criteria for RCT participants are shown in Table 1

Table 1. Inclusion Criteria

Criteria	Inclusion	
	Fathers	Sons
Age	18 yrs. of age and over	11 to 17 yrs. of age
Language	Ability to speak and understand Spanish	Ability to speak and understand English or Spanish
Community residency	Living in the urban or semi-rural areas of Miami Dade such as Homestead, Naranja or Florida City who will remain in area for 6 months or working in the work industries described below or	Who will remain in area for 6 months
Jobs	Working in the farm industry, nurseries, sales, construction, truck industry, landscaping, self-employed or other work industry. Unemployed fathers are also eligible.	

Consent	Able to understand & provide consent	Able to understand & provide assent and has parental consent
Dyad	Be considered a father/father figure to participate [1, 2]	Preferably the youngest eligible of sons [2]

1. *In cases where men have more than one son that meets the inclusion criteria, attempts will be made to recruit the youngest son, which will allow prevention measures as early as possible.*
2. *In cases where the adult male is not the legal guardian, written consent from the child's legal guardian will be required in addition to assent from the adolescent.*

6) Number of Subjects*

Aim 1

The number of participants for in-depth interviews will be no more than 20. The number of participants for the focus groups will be 48. i) 2 focus groups with fathers (n=16) ii) 2 focus groups with youth (n=16) iii) 2 focus groups with community leaders (n=16)

Aim 2

Number of participants will be N=320

iv) 160 dyads

v) n=160 fathers vi)

n=160 sons

7) Study-Wide Recruitment Methods*

Aim 1: Seasonal farmworkers, people (adult men, women, and youths) working in the farm working community (or adolescent child of a farm worker), nurseries, and leaders of the farm working communities will be sampled, in part, through community-based agencies serving the Latino seasonal farmworker (LSFWs) families of MDC. In addition to referrals from our community partners, we will conduct recruitment efforts in locations frequented by male LSFWs and their families, including local farmworker camps, Latino festivals, health fairs, soccer fields and other parks, social service agencies, and health care facilities. Various methods may be used to recruit participants including study flyers, dissemination through social and mass media outlets, and word of mouth. Recruitment efforts for the focus groups will be coordinated with CBOs which will identify additional stakeholders via partnerships with faith-based organizations, youth and recreational organizations, and other service providers in the seasonal farmworker community. We will also recruit via presentations and other previously successful strategies used by our community outreach team in areas where farmworkers live, gather, socialize, and work.

Aim 2: Various methods will continue to be used to recruit participants. We will send flyers to agencies' program coordinators and other contacts in urban communities, community leaders, and nurseries to recruit participants for the study. Participants recruited into the study via word of mouth and radio ads will be asked to refer other participants and provide the contact information of men who may meet eligibility criteria

using a respondent-driven sampling (RDS) approach, which is an effective strategy to recruit participants from hidden populations.
In RDS, each participant (seed) will be asked to refer up to three other individuals in their social network who meet study inclusionary criteria. Seeds will be compensated twenty ($20.00 dollars) per each eligible participant who enrolls in the study. This procedure will be followed for three legs for each initial participant (seed) at which point a new seed will begin in effort to avoid skewing the sample**.**

In addition to the recruitment strategies used for Aim 1, we will be recruiting using telephone outreach calls to previous community gatekeepers in the urban areas and extant participant's pipeline. The electronic and telephone calls, and voicemails outreach approach may be a temporary measure due to the 2019-2020 Coronavirus Pandemic.
Presently, we will be conducting recruitment remotely. Additionally, we will continue recruiting vial local radio stations, social media, online resources and different technology venues available to reach the urban and the semi-rural community. These recommendations will be followed for the safety of participants, staff and the community.

8) Study Timelines*

The timeline shown in Table 2 is the intended timeline. Some of the activities may not be completed within the proposed time.

Aim 1. After the study protocol has been approved by the IRB. Participants will be recruited for the focus groups and interviews. Focus groups and interviews will be facilitated by trained protocol personnel and transcription will commence immediately after data collection as shown in Table 2.

Aim 2. After potential participants are identified and screened for eligibility, a meeting will be scheduled to complete informed consent procedures and baseline assessments. Father-son dyads interview time and dates will be scheduled simultaneously and will be interviewed separately in order to maintain confidentiality. Once dyadic groups are interviewed, they will be entered into the study in waves of 20 dyads to avoid delays between recruitment, randomization, and intervention delivery. Intervention sessions will be scheduled based on participants groups availability (6-8 fathers will be invited to participate per group session for the control and the intervention). Control and intervention groups will be conducted within the same time frame (participants eligibility includes being available for the intervention group and the control group).
During the temporary social distancing, the assessments for both fathers and sons will be completed remotely; fathers will be interviewed by telephone and adolescents will receive a well-proven secured link to complete the questionnaire or may be interviewed by telephone. There will be an interviewer available to ensure the completion of the baseline assessment and answer any questions the participant may have.

Table 2. Timeline of HoMBRES de Familia depicted in a quarterly fashion.

	Year 01				Year 02				Year 03				Year 04			
Proposed activities (quarterly basis)	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Develop focus group protocol/recruitment	■	■	■	■												
Conduct focus groups	■	■	■	■												
Qualitative data analyses of focus groups		■	■	■												
Develop key informant interview protocol		■			■	■										

Conduct key informant interviews					■	■										
Qualitative analyses of key informant interviews				■	■	■										
Adapt intervention				■	■	■										
Recruit, hire and train staff				■	■	■										
Training of peer-advocates					■	■										
Pre-test adapted intervention					■											
Recruit participants					■	■										
Baseline assessments (Tx. & control)						■	■	■	■	■	■	■	■			
Implement intervention						■	■	■	■	■	■	■	■			
6 month post-tests							■	■	■	■	■	■	■	■		
Fidelity and process evaluations						■	■	■	■	■	■	■	■	■		
Analyze intervention efficacy, evaluation reports												■	■	■	■	■
Dissemination of research findings															■	■

9) Study Endpoints* NA

10) Procedures Involved*

Aim 1:

Focus groups and in-depth interviews will provide qualitative data on community capacity, feasibility, and acceptability of the HoMBRES de Familia intervention and provide information on the adaptations needed to culturally tailor it to the target community. We intend to conduct a total of 6 focus groups (n = 48): 2 with men (fathers), 2 with adolescents (13-17 years old), and 2 with community service providers/ stakeholders (e.g., representatives from community service providers and local farmworker organizations, faith-based organizations, community health centers, advocacy centers, and other service providers).
We intend to also conduct up to 20 interviews with community leaders (business owners, day care providers, farm working supervisor and others) who did not participate in the focus groups.

Focus groups and interviews will be conducted by bilingual trained protocol personnel, audio-recorded, and transcribed verbatim for analysis (in the language they were conducted) using N-vivo. For each focus group, participants will determine whether the focus groups will be conducted in English or Spanish. We anticipate that adolescent groups will prefer English and adults will prefer Spanish. Interviews (40-60 minutes) will be conducted in English or Spanish according to the participant's preference. A semi-structured in-depth interview guide will be developed based on previous formative research, using questions from the focus groups and focus group findings.
The data from Aim 1 will provide the foundation for adapting and pre-testing the HoMBRES de Familia intervention. A subsequent quantitative evaluation of the adapted intervention's efficacy (Aim 2) will be completed via a 2-arm randomized control trial (RCT) with a sample of 160 father-son dyads (N=320)

Aim 2:

The 2-arm RCT will test the efficacy of the adapted intervention with a sample of 160 father-son dyads (N=320). After potential participants are identified and screened, a

meeting will be scheduled to complete informed consent procedures and baseline assessments. Father-son dyads will be entered into the study in waves of 20 dyads to avoid delays between recruitment, randomization, and intervention delivery. Father-son dyads will be randomized into the intervention or control condition using the computer software RANDI2. Randomization will be done using the dyads ID after pre-test. Father-son dyads will be randomized into the intervention (HoMBRES) or control condition. Adolescents will only be expected to participate in baseline and 6-month follow up assessments, as the intervention program is solely parent-based.

A locator form completed by each participant father during the baseline assessment will guide initial attempts to contact participants. This screening form will contain two or three local phone numbers associated with the participant (father), the address where the participant lived when interviewed, email address, social media contact information. We will also use the following retention strategies as needed: (1) send a letter to participants seeking their continuous participation in the study; (2) contact participants by email; (3) conduct home visits if we cannot reach participants by phone or email; (4) make up to monthly phone calls to ascertain if there are changes in contact information or address; (5) use corroborative contact sources (from locator form); and (6) maintain routine contact with participants through project newsletters or cards for birthdays or US/Latin American holidays. If participants cannot be reached by the above methods, we will use online phone directories, Internet search engines, and social networking sites to locate updated contact information. Only adults will be searched/contacted in this manner. A combination of postal mail, email, and text reminders and confirmation calls will help minimize missed appointments.

HoMBRES Intervention. Due to the outlined measures above, the intervention HoMBRES will consist of four sessions remotely facilitated via a well-tested video platform accessible by a link sent to the participants' telephone, computer, tablet or IPad (approximately 1.5 hours each session) during the period of social distancing, and perhaps beyond if we find that the remote sessions are working well. Intervention videos will be followed up with a telephone call to respond to any questions participants may have about the sessions and clarify (if needed) the material covered in the videos via telephone or text messages. Staff will schedule the times when participants will watch the videotaped sessions in order to be available for their questions. Topics covered across the modules/ sessions are shown below. Participants will also be provided with a resource application (app) and online link with a list of community service providers related to substance abuse, HIV/AIDS, and violence.

<u>Hombres Intervention modules</u>:

Module1:

- Program introduction/ Parental cultural influence on adolescents Module 2:
- HIV prevention and STIs and sexual behaviors
- The role of parents as educators/ the role of educators in the community

Module 3:

- Talking to your son about sexual practice and relationships
- Alcohol and drug prevention

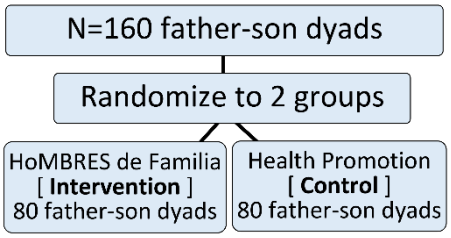
Module 4

- Domestic violence prevention/Father as educator
- Class Review

- Parents feedback and evaluation

Health Promotion Control. Fathers randomized to the control group will receive a Health Promotion /Diabetes Prevention intervention guided by the CDC recognized Prevent2 program.64 The diabetes prevention lifestyle program will be provided to the fathers in a secured link or website platforms accessible from a phone, computer, tablet or IPad. The session will be 1.5 hours approximately. Session content will focus on the importance of physical activity, healthy eating, and maintaining a healthy weight. Fathers will receive information to share with their participant sons and other family. The intervention will not include discussion on SAVA-related factors in the population.

Figure 1. Research Design [Noonly father participants in the interventions]



Assessments. Baseline data will be collected for fathers and sons in both the intervention
and control group prior to initiating the intervention followed by a 6month follow-up assessment. During the time of social distancing data (for baseline or follow-up assessments) will be collected via telephone calls, FaceTime application, WhatsApp or other remote alternative venues. When CDC recommends that social distancing is no longer necessary, consenting and interviewing may be done by phone or face to face as per participant request. Survey data will be collected utilizing Apple iPad tablet computers and REDCap (Research Electronic Data Capture; survey and data management software). Pre- and post-test for the fathers will be collected using an interviewer administered assessment. Interviews are culturally congruent with our target population—given that some Latinos value *personalismo*, a cultural feature that values cordial interactions and interpersonal engagement. Interviewer-administered assessments will help mitigate any issues related to poor literacy. The interview with the adolescents will also be remotely administered at baseline and 6 months follow up, using a REDCap link sent to the participants accessible on their phones, computers, tablets or IPads or by telephone. Study staff will be available via telephone to assist adolescents in completing the assessment. Survey administration will take approximately 1 to 2 hours for the fathers and 1 to 1.5 hours for the youth.

Measures:

The following table includes a list of the measures that will be utilized during the baseline and the 6-month follow up of the study:

Table 1. HoMBRES Measures

CONSTRUCT	MEASURE	Tested Dyad Member*
Risk and Protective Factors		

▪ Culture-Related Risk/Protective Factors to be Considered in Cultural Tailoring of Interventions		
Cultural Values	Mexican American Cultural Values Scale	FY
Gender Roles	Machismo and Caballerismo Scale	FY
Culture-Related Stress	Hispanic Stress Inventory 2; Hispanic Stress Inventory for Adolescents	FY
▪ Risk/Protective Factors that are Potentially Malleable Targets for Intervention		
Health Literacy	Health Literacy Screening Questionnaire	F
HIV Knowledge	HoMBRES Brief HIV Knowledge Questionnaire	F
Self-efficacy	Self-Efficacy for HIV Scale	F
Attitudes about Sex	Measure of Sexual Attitudes and Behavior	FY
Parent-Child Relationship	Family Connectedness Scale	FY
Family Functioning	Family Environment Scale Parenting	FY
Parental Monitoring; Parent-Child Communication	Practices Scale	FY
Moderator Variables		
Demographics	El Centro Demographics Form	FY
Neighborhood Disadvantage	PhenX Toolkit Neighborhood Concentrated Disadvantage	F
Neighborhood Safety & Support	PhenX Toolkit Neighborhood Scales: Collective Efficacy, Safety	FY
Acculturation	Bidimensional Acculturation Scale for Hispanics[8]	FY
SAVA Indicators		
Substance Use/Abuse	Timeline Follow-back	F
Trauma Exposure	PhenX Toolkit Exposures to Violence; Immigration Trauma Items	FY
Psychological Distress	Patient Health Questionnaire (PHQ9)	F
Sexual Risk Behavior	PhenX Toolkit Sexual Risk Behavior	F

*Denotes whether measure will be given to Father (Y) and/or Youth (Y) among father-son dyad members

Telephone contact assessment. There will be a telephone contact at 2-3 months after the first session of the intervention in which a study team member will contact participant fathers. Some of the questions will be the following:

1. How have you been in the last several weeks?
2. Have you been talking to your son about any issues related to the program?
3. Has there been any changes in your living arrangements? In your family?

4. Have you been working in the last month?
5. Are you planning to move soon?
6. Have you shared any information from [the intervention] with anybody among your family or friends?

11) Data and Specimen Banking*

Not applicable

12) Data Management*

All paper data will be kept in locked file cabinets in locked project offices at FIU and will be accessible only to study staff. Staff from the Integrated Biostatistics and Data Management Center at FIU will develop and test all data collection and quality control processes and create a REDCap database. Access to REDCap is secure, and all data will be backed up within a secure data center (see Facilities and Other Resources).
Quality control will be enhanced through REDCap's built-in quality checks and mechanisms to detect inappropriate values on questionnaire items. The project statistician will work closely with study staff to export the REDCap data to statistical analysis software loaded on the project's HIPAA-compliant computer. All audio recordings will be transferred to a computer, transcribed verbatim, entered into standard word processing files, and verified. De-identified qualitative data in the form of transcripts will be returned to the Project Lead (Dr. Rojas) and Co-Lead (Dr. Sanchez) by the transcriptionist on a regular basis and kept in locked file cabinets. Audio files will be deleted from the digital recorder immediately after successful download. The files will be converted into data files compatible with Atlas.ti. Focus groups and interviews will be transcribed and translated by trained bi-lingual study staff or through an IRBapproved transcription service.
Qualitative Data Analysis Bilingual coders will transcribe in-depth interviews (IDIs) and focus groups (FGs) in the language in which they were conducted. For the focus groups and in-depth interviews, we will use a constant comparison analytic strategy; we will develop a preliminary codebook after reviewing the first transcript. Two independent coders will code each text segment and compare coding, discussing and resolving any areas of discrepancy. Disagreements will be discussed until consensus is reached. Although this analytic approach is time consuming, its implementation will help minimize coding bias. The primary codes identified across the focus groups and moderator notes will serve as the basis for the textual content of the new intervention.

Quantitative Data Analysis Plan In testing the efficacy the HoMBRES de Familia intervention, we will utilize a 2-arm RCT employing intent-to-treat analysis using the initial group assignment, without considering the number of sessions that participants attend. We will run descriptive analyses at baseline for sociodemographic variables including age, country of birth, education, income, and marital status, and assess the differences between intervention group and control group at baseline using t-test for continuous variables and Chi-square test for categorical variables. We will test the efficacy of the intervention on individual outcomes (substance use, family violence, HIV) to examine how each component of the SAVA syndemic was independently impacted. We will use linear mixed model for continuous outcomes and generalized linear mixed model for categorical outcomes at follow-up, while adjusting for baseline measures, sociodemographics, and potential cluster effect among groups in intervention group and father-son dyads.

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Version HoMBRES de Famlia (HoMBRES) #1

13) Provisions to Monitor the Data to Ensure the Safety of Subjects*

All aspects of the Research Project implementation will be governed by Research Project Lead (Dr. Rojas) with assistance of Project Co-Lead (Dr. Sanchez) or Project Coordinator (Mrs. Canedo) under the monitoring of the Protocol PI (Dr. Behar-Zusman, formerly known as Dr. Mitrani). Data quality assurance procedures will be done by a trained staff member. Researchers will monitor and follow-up and report as required suicidality ideation and child as well as elderly abuse.
The study will be monitored by the CLaRO Study Monitoring Unit which is based at the UM School of Nursing and Health Studies. The Study Monitoring Unit will (1) verify compliance with regulatory requirements, (2) ensure that the Project Leads and staff (including those at community agencies) are fully informed of regulatory requirements and properly trained to perform the duties assigned, and (3) monitor procedures to prevent errors and minimize protocol deviations that can negatively affect quality of the data collected and compromise human subjects' protection. The project will have a quality assurance (QA) review: prior to initiation, upon conducting baseline procedures with the first wave of study participants; and bi-annually for interim reviews.

Adverse Events and Serious Adverse Events (AE and SAE): The Project Lead and protocol PI will be responsible for monitoring and reporting and comply with the reporting requirements of the IR B and NIMHD. The Data and Safety Monitoring plan will have required reports will include any adverse events as well as the results of analysis conducted. The PI and Project Lead will ensure that any AE or SAE are timely reported to the IRB.

During the study implementation, we foresee that they may be certain events with the families such as: 1) domestic violence; 2) work contract was terminated and participant has to move to another city; 3) entire family is moving to another estate; 4) father moved out of the home; 4) father was kicked out of home.

Among the Serious adverse events (SAE) we may encounter: 1) physical abuse with partners and adolescents, 2) hospitalization, 3) substance abuse.
All assessments conducted by the study's interviewers are opportunities for identifying adverse events if reported by the participant and/or a family member. The educators will be trained to identify AEs and SAEs at session of the intervention and at each interview or assessment points. Additionally, anytime during the study, a participant or his/her family member may report an AE/SAE to their group facilitators/educators. These events will be identified, classified as serious or not**,** and will be handled in the same manner as AEs/SAEs during the formal assessments.

Study personnel (including peer advocates) will be trained to identify adverse events, and categorize serious adverse events, based on direct reporting during sessions. Upon identification of an adverse event, the team member should notify the study coordinator who will assess the event for seriousness to guarantee that appropriate care and reporting occur within approximately 24 hours. As soon as an adverse event is identified either by querying or direct report, the event will be recorded in the AE log. In addition, the Project Lead (Dr. Rojas) or Co-Project Lead (Dr. Sanchez) or Project Coordinator (Mrs. Canedo) will be notified of any and all AEs. In both treatment conditions, action may be taken by the peer advocate to respond to non-serious events (e.g., referral to counselor, community program, local agency or hospital). The

Project Lead or CO- Project Lead are responsible for conducting further evaluations and completion of the AE log.

In addition to the SAE's listed above, SAEs will include all issues that involve imminent danger to self or other. In cases of current suicidal, homicidal, and abusive behaviors, participants in both conditions will be immediately referred to the Open-Door clinic or to the local emergency room in order to ensure that appropriate crisis intervention services are provided. The reporting procedures for SAEs experienced by any participant in the study will be in accordance with the UM IRB reporting policy. When an SAE occurs, the Project Lead and the PI must be notified when possible within 2 hours of identification. The PI, in consultation with the Project Lead will be responsible for assessing relatedness to the intervention and forwarding the report to the UM IRB and NIH as required.

Safety will be assessed using two principal Safety Assessment Strategies: (1) incident and adverse event monitoring through a passive system, which will entail reporting using a form that details the various reportable event categories, and an (2) active system, whereby Dr. Rojas will, on a weekly basis, determine if any reportable events occurred. The events reportable through the active and passive adverse event monitoring system include: (a) unauthorized disclosures or breaches of confidentiality; (b) threats or acts of violence or self-harm; (c) acts of negligence and violence against a minor or an elderly person. Interviews with participants will ensure the report of suicidal ideation, family violence, or other sentinel events.

14) Withdrawal of Subjects*

Subjects may choose to withdraw from the study at any time. We will discontinue data collection on the withdrawn subject and will use the partial data collected with participant's permission. Participants will be told that their participation in the study may be stopped at any time by the investigator without their permission. Subjects will be withdrawn by the PI (in consultation with the Project Lead) if their safety is endangered by attending the intervention groups. Reasons for withdrawal may be if the participant appears to be extremely distraught by the discussion in the group sessions or if the participant threatens to harm himself or others.

15) Risks to Subjects*

Overall, data collection and intervention in the HoMBRES study presents minimal risks for participants. All of the steps that may be taken to protect the well-being of participants or their family members deemed to be in danger will be described fully to all participants and we will do everything possible to minimize harm to the youth, family or any of its members. The following are possible risks for the participants divided by the study's aims:

Aim 1**:** During the focus group sessions, participants might reveal highly sensitive information regarding their substance use, sexual behavior, and HIV status; there is a potential risk for breach of privacy and confidentiality regarding these sensitive topics. There is also a risk that some questions may distress the participants. In order to prevent those risks, all participants will be briefed on the issues of confidentiality. Participants will be asked to avoid using their names or naming others and will be asked to maintain the confidentiality of other focus group members. Identifying information will be redacted from transcriptions.

Aim 2**:** No side serious side effects have been noted in the current literature in association with the behavioral questionnaires, interviews, and interventions used in this study, although, as with many assessment batteries, some people may experience mild fatigue or momentary concern about their ability to do well. Although there are no specific questions regarding abuse and neglect of minors or elderlies in the baseline or posttest assessments, there is a risk that participants disclose abuse and other reportable behavior during the assessments or during the interventions. Interviewers will be trained to identify cases of child and elderly abuse (sexual, physical and emotional).
Training will include providing them with a battery of the appropriate questions to ask participants when they report physical punishments, negligence, or sexual abuse. Participants will be reassured that their confidentiality is safe and will be informed that due to federal regulations and Florida statues we are mandated reporters.
Interviewers and facilitators are informed also that an incident report needs to be filed within 48 hours.

There is a risk that some of the questions may distress the participants. Adult participants will be asked to provide information about highly sensitive topics such as substance use, sexual behavior, and HIV status. The measures with sexual or substance use questions completed by the youth are gated so that children to limit their exposure to sensitive topics.

During the intervention participant may feel shy or may not feel comfortable talking about certain taboo issues. Additionally, by participating in this research project, participants may become aware of or sensitized to their HIV risks, family violence, risk for a substance use disorder or other health risks. In order to decrease feelings of comfort, participants will be told to speak in a third person.

Providing incentives to participants may inappropriately persuade them to participate in research— pressure that may meet criteria for coercive recruitment, especially because most of those who will participate in the proposed Research Project are persons of very low income.

There is a potential risk for a breach in data security that may infringe on the participant's privacy and confidentiality regarding these sensitive topics. As an NIH sponsored study, the study will automatically be issued a Certificate of Confidentiality. Participants will be made aware that there could be a breach of confidentiality by other participants who might be aware of their participation in the study, given the sampling methodology. However, they will be assured that no data will be linked to their personal information.

Aim 3**:** The specific procedures for Aim 3 are to be determined

16) Potential Benefits to Subjects*
Aim 1**:** *There are no direct benefits* to participant, *however* participants may occasionally experience a sense of relief or satisfaction discussing barriers that they face in the community.
Aim 2**:** Benefit participants may receive is referral to services as needed. Participants randomized to the HoMBRES intervention may increase their skills of communicating with their adolescent sons and their knowledge about HIV, substance abuse and domestic violence. Participants randomized to the control intervention may increase their knowledge about health promotion and diabetes prevention.

Aim 3**:** We do not anticipate direct benefits to participants*;* however, the community at large may benefit from learning about an intervention for Latino parents that may help men and their sons. Participants will be able to share the results of the intervention with other members of their community and advocate for similar programs from local agencies.

17) Vulnerable Populations*

The youth (ages 11-17) who will participate in this study will be required to have their parent/legal guardian consent to participate and additionally will meet the regulatory requirements described in the HHS regulations, Subpart D. All the consent and assent forms will be submitted to the UM IRB for review and approval. All the adolescents will sign an IRB approved assent form before participation.

The proposed study aims at increasing education and HIV prevention skills among adult men and their adolescent sons, therefore, including youth in the assessment portion is critical for testing the effectiveness of the study.

The intervention HoMBRES was developed for farm working men, a socio-economically vulnerable population, and therefore the researchers will take all the necessary precautions to ensure confidentiality and avoid coercive approaches. The entire research team has conducted various NIH funded studies and a couple of interventions for this vulnerable high-risk minority population.

Participants will be explained the consent and assent forms in order to ensure that they understand the protocol and will be encouraged to ask questions.

Aim 2: Participants will be encouraged to ask questions during the interventions and will be asked to provide feedback regarding their experience as well as evaluating the sessions. Sessions will be randomly supervised for quality control during the duration of aim 2.

18) Multi-Site Research* NA

19) Community-Based Participatory Research*

Researchers will be working with various community organizations such as the Farm Workers Association and the Coalition of Florida Farmworkers Organization (COFFO) to recruit and facilitate interventions. These community partners will help us recruit participants for the focus groups which will guide the adaptation of the intervention

Partners from the community will be asked to provide feedback about the intervention during the CAB meetings.

20) Sharing of Results with Subjects*

Under Aim 3, dissemination of the study findings will be accomplished in close collaboration with the Community Engagement and Dissemination Core of CLaRO (parent NIH contract for this study).

Strategies for providing relevant information to the LSFW community: Under Aim 3 dissemination strategies will be performed in areas where LSFWs gather, socialize, and celebrate. In MDC, this includes local flea markets, recreational parks, Latino festivals, health fairs, and places. Dissemination activities will include: (a) Presentations to community stakeholders and service providers involved in addressing substance abuse, family violence, and HIV/AIDS in the local community, and (b) Distributing information to the local community via informational booths at local health fairs and ethnic festivals.

21) Setting

Procedures for Aims 1 and Aims 2 will be provided in private community settings including the COFFO offices as well as the Everglades Community Center and Redland farm camp community center or other locations in the urban, semi-rural areas of Homestead, Naranja and Florida City or other locations within walking distance or short drive of participants homes. During the COVID-19 Pandemic, procedures of Aims 2 will be conducted remotely as described above. Once dyads are interviewed, they will be sent a private link with the video sessions based on the group randomization. This approach will help us avoid delays between recruitment, randomization and intervention delivery. Interventions will be facilitated via a secured link. The webinar style video will be solely available to participants using a private link (ie. Zoom, youtube, powerpoint and other venues available to the participants). These venues can provide privacy and confidentiality.

Incentives for participation will be delivered by money order, electronic cash deposits or payments such as Zelle or another electronic platform preferred by participants
It should be noted that participants in this study are of very limited financial means and may not all have access to platforms used at UM (e.g., Zoom), furthermore, we are trying to use means of communication that participants are accustomed to. We will have to assess their technology and will proceed accordingly, using the UM platforms as first line, but may need to use other means of communication and transmission as per participant access.

22) Resources Available

This project is being conducted as part of the Center for Latino Health Research Opportunities (CLaRO), which is funded by the NIMHD under a U54 contract. CLaRO is led by Drs. Victoria Behar-Zusman (UM PI) and Mario de La Rosa (FIU PI). CLaRO is a cross-institutional partnership rooted in shared commitment of UM and FIU to address ethnic/racial and sexual/minority health and health disparities through research and community engagement, and commitment to nurture the careers of the next generation of health disparity scientists. The PIs have decades of experience as health disparities researchers focused on Latino populations and as mentors dedicated to diversity in the scientific workforce; they share a common vision for the mission of CLaRO. Dr. Behar-Zusman is researcher in family-based behavioral interventions, family process and measurement with families of adolescents, women, and seniors, and with extensive experience in regulatory, research conduct, and human subjects' oversight. Dr. De La Rosa is a researcher in substance abuse and HIV with recent Latino immigrants, Latina mother-daughter dyads, and Latino seasonal migrant workers—including the development of HIV prevention interventions targeting the HIV risk behaviors of Latina seasonal migrant workers. Dr. Behar-Zusman will serve as the protocol PI. Resources of CLaRO that are available to this study include the Administrative, which will provide

assistance for monitoring of human subjects' protection, quality assurance, measures, and research administration, and the Community Engagement Core which maintains a CommunityScientific Advisory Board, which will be instrumental in Aim 3 of this protocol.

The study team qualifications:

Dr. Rojas – Project Lead

Dr. Rojas has several years working in the field of health disparity with the target population in the current study. She is knowledgeable about the community and the HoMBRES study is a progression of a past study targeting adult women. Dr. Rojas is a bilingual and bicultural researcher who has experience in data collection, community - based research and interventions with LFWS. Dr. Rojas has supervised intervention studies and has worked with adolescent studies in the past. Dr. Rojas research aims to understand health behaviors among Latino adults, family health correlates related to health behaviors.

Dr. Sanchez – Co-Project Lead

Dr. Sanchez has been a contributing to the data collection instruments for Dr. Rojas' studies and also has assisted in the translation and backtranslation of instruments and consent forms for several studies in the past. Dr. Sanchez is an avid researcher who has been working in health disparity for the last decade. Dr. Sanchez has extensive experience in establishing good working relationships with referral sources and other community partners.

Dr. Cano – Co-Investigator

Dr. Cano's research focuses on Latino adolescent health behaviors and family function. He has published extensively on the role of family attachment and family functioning on Hispanic adolescents. He has conducted preliminary studies on recent born in the community as well as adult women. His research aims to reduce health disparity among Latinos in the areas of mental health and substance abuse.

Marisabel Canedo- Project Coordinator

Mrs. Canedo has experience coordinating longitudinal studies at University of California, Los Angeles and University of Miami. She is bilingual and has worked in several studies as group facilitator, community recruiter, interviewer with the Latino communities in Los Angeles and Miami. Mrs. Canedo will provide support to the project lead and co-leads, will oversee the administration of protocol for data collection in Aim 1 and Aim 2, will be back up for interviews and will conduct daily administrative duties.

Maria Khalona - **Community Researcher**

Ms Knalona has extensive experience conducting studies in the target community. She will be in charge of building rapport with community leaders and assisting in the recruitment and retention. We anticipate that recruitment of the target sample will be feasible given that accessibility to the sampling frame should be more than sufficient. As with most LSFW communities, most seasonal farmworkers in MDC are males. In addition, our community partner provides many adolescent-centered programs in the LSFW community. Ms. Khalona is working closely with three group facilitators and outreach workers.

Selection, training, and supervision of research staff: Research staff on the protocol are experienced in research with the Latino community and Latino males and will be trained in all relevant aspects of the protocol.

23) Prior Approvals
FIU has authorized the UM IRB to be the IRB of record for this study

24) Recruitment Methods
As described in section 7, participants will be recruited through a variety of methods including word of mouth, flyers, radio add, community agency collaborators as well as active outreach in the different activities in the community.

25) Local Number of Subjects
Aim 1: Sixty-eight (N=68) participants will be sampled in the focus groups (n=48) and the interviews (N=20).
Aim 2: The total number of subjects in the intervention will be 320 (160 father/son dyads).
Aim 3: To be determined

26) Confidentiality
The issues surrounding confidentiality are of supreme importance and sensitivity because highly personal clinical information will be obtained from the fathers and adolescent sons in Aim 2. Adult participants will provide written consent attesting consent to their understanding that the information they provide will be held as personal and confidential to the extent permitted by law. Youth will provide written approval to the assent form that explains the limits of confidentiality. Consent and assent forms will clearly state the right to refuse participation at any time. Further, the refusal to participate will not influence any of the services the adolescent or his/her family may receive. In addition to the confidentiality assurances, the participants in the study are protected by a Certificate of Confidentiality under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d), authority delegated to the National Institutes of Health (NIH).

Regarding data and other records confidentiality, researchers will follow the UM established set of procedures designed to ensure the protection of confidentiality. All project staff will be specifically trained on issues of confidentiality. Due to the use of the web-based REDCap system we anticipate that there will not be any hard copies of data and all the documents pertinent to the study such as consent forms and contact information will be stored in a locked cabinet at the FIU Center for Research on US Latino HIV/AIDS and Drug Abuse (CRUSADA) offices overseen by CLaRO PI, De La Rosa and protocol lead, Dr. Rojas. Passwords are used to restrict entry into the REDCap database. There will be very few documents with identifying information (consent forms) and all documents with identifying information will be stored at the in locked file cabinets within a locked office in the PI office and the project director's office. It should be noted that in our years of clinical research (over 14 years), not a single incident of violation of confidentiality has occurred.

The technology system that will be used in the study will collect usage data that will be securely housed on the project servers. Data will be collected without requiring that the participant actively send them. Data collected in real-time do not contain names or identifying information, only case numbers. In addition, the system will require a

password to see messages sent to the participant. Physical access to servers at the Data Center are controlled by security systems, intruder alarms, and monitored by the Department of Security video surveillance/recording systems. At FIU, the Data Center provides appropriate environmental control via HVAC systems, uninterruptible Power Supply and emergency generators to maintain power without interruption, The Data Center also provides secure backup for all data systems.

The study will be monitored by the CLaRO Study Monitoring Unit which is based at the UM School of Nursing and Health Studies. The Study Monitoring Unit will (1) verify compliance with regulatory requirements, (2) ensure that the Project Leads and staff (including those at community agencies) are fully informed of regulatory requirements and properly trained to perform the duties assigned, and (3) monitor procedures to prevent errors and minimize protocol deviations that can negatively affect quality of the data collected and compromise human subjects' protection. The project will have a quality assurance (QA) review: prior to initiation, upon conducting baseline procedures with the first wave of study participants; and bi-annually for interim reviews.

27) Provisions to Protect the Privacy Interests of Subjects

As explained previously, interviews will be done in a private setting chosen by the participant. Data will be entered to RedCap in a password protected IPad. Data will be only available to researchers approved by the IRB and to the study monitoring unit. Participants will be reminded of their ability to stop the interview or refuse to answer questions that make them uncomfortable. During the recruitment and consent/assent process, and prior to any data collection, participants will be assured that their information is confidential, and will only be accessed by study staff members. As described above, participants will sign a statement attesting to their understanding that their information will be kept private and confidential to the extent permitted by law. Participants know that they will be assigned unique case numbers (and that their names will not be used) to protect their identity. For telephone data collection, participant will be asked to choose a quiet and private area where he can answer questions while keeping confidentiality. Whenever, possible and as per participant preference, he will be interviewed via videoconference to increase the rapport and ensure privacy.

28) Compensation for Research-Related Injury

N/A

29) Economic Burden to Subjects

Aim 1: Participants may incur costs associated with transportation to and from intervention sessions. However, most participants will live within walking distance to the program location. Participants will be compensated to offset their expenses.
Aim 2: We do not anticipate that the participants will endure any financial cost as the recruitment, consenting, and intervention will be provided using digital venues and participants will be able to complete the study from their homes. To further prevent participants' financial burden, we will suggest free telephone applications such as WhatsApp. When the CDC recommends that social distancing is no longer necessary, consenting and interviewing may be done face to face as per participant request. Additionally, when social distancing restrictions are no longer active, UBER services would be available for participants who report transportation difficulties to get to interviews.

FIU entered into an agreement with Uber Health to help with transporting research participants from their homes or work or preferred location to the research sites and return. According to Uber Health, they take healthcare patient and confidentiality seriously and already treat research participants in the same manner. To handle Protected Health Information (PHI) with appropriate care, they've built HIPAA compliance into Uber Health from the ground up. According to Robert L. Chaput, CEO Clearwater Compliance, "In June 2017, we conducted a HIPAA Risk Analysis of the technical, physical, and administrative controls related to Uber Health's new dashboard and technology. Our team concluded that Uber Health has an unusually robust security environment involving numerous information security safeguards." Uber Health states that they have a HIPAA-trained Uber Health team dedicated to building technology for healthcare and that rider information is encrypted as a safeguard for handling PHI when ordering rides for participants. Uber signed a Business Associate Agreement (BAA) with FIU and under the BAA, Uber is committed to performing steps, which safeguard and protect PHI. When a driver receives an Uber Health trip request, it is indistinguishable from any other type of Uber request to protect patient privacy.

The internal infrastructure of the Uber's data storage:
"Uber Health applies an information security defense-in-depth strategy where layers of technical and administrative controls are deployed and then validated by user access and activity reviews, alerting, deployment of near-universal two- factor authentication, and use of encryption. Ongoing monitoring provides reasonable assurances that only authorized users have access to the Uber Health environment. Uber Health and Uber Technologies have implemented numerous information security safeguards that are considered industry best practices, including but not limited to: authentication, password management, expiring certificates, imaging, encryption, internal monitoring and reporting, role-based access and disaster recovery. Uber Health's ePHI is stored within a reputable, HIPAA-compliant thirdparty cloud environment to which physical access is highly restricted and monitored, and in transit ePHI in the Uber environment is subject to encryption and strict administrative and technical controls." In addition, Uber has controls in place to make sure only the necessary individuals within FIU can see participants' information. Administrators and billing contacts will only receive a sum total of the money spent on rides and a transaction list of each ride leading up to that amount. The coordinators within FIU who are arranging the rides would only be able to see the rides they order themselves and not of others.

30) Consent Process

Aim 1: All participants will provide their consent (or assent as applicable) prior to participating in the interviews and focus groups. Participants will be given a consent (or assent) form which will be read to them by a study team member in their preferred language (Spanish or English) as some of our participants have a very low literacy level. The consent process will either take place in a group or individual format. Participants will be encouraged to ask questions regarding any aspect of the study and the study personnel will answer these questions. Participants will keep a copy of the consent/ assent forms.

Aim 2. After potential participants are identified and screened, a meeting will be scheduled with the father-son dyads to complete informed consent/assent procedures and baseline assessments. Fathers and adolescents will be read the consent/assent forms for the reasons explained previously. Participants will be encouraged to ask questions regarding any aspect of the study and the study

personnel will answer these questions. Once all questions are answered the participants will be asked to provide written approval to the consent/assent form. Once the minor turns 18 years old, a new consent form will be read and requested to provide written approval by such participant. In cases where the adult male (father) is not the legal guardian, written consent from the child's legal guardian will be required in addition to assent from the adolescent.

As result of the social distancing recommendations, eligible participants will be contacted via telephone, FaceTime apps, WhatsApp, telephone or video call to read the consent form. Consent will be read to eligible participants over the phone with two staff members present (one listening on the speakerphone who will sign as a witness to the consenting). The participant will also be given the option of having a witness on his side of the phone. If a potential participant agrees to participate in the study, he will provide verbal consent which will have the signature of the staff obtaining the consent and the witness. Then 2 copies of the consent with signatures will be emailed, texted or mailed as per participant choice of delivery. This will be sent with a stamped return envelope for the participant to sign and return to the research team. The same procedure will be used for the consenting of the legal representative and the assenting of the youth. Father-son dyads interviews (time and date) will be scheduled simultaneously, and they will be interviewed via phone separately in order to maintain confidentiality. A staff will conduct the interview with the father using any available venue for the participant (Phone or video conference). Since the adolescents are self-administering the questionnaire, they will receive a RedCap link to the questionnaire on their telephone, computer, tablet or IPad so they can respond to the measures. The adolescents will also be given the option of phone interview. A staff member will be available to guide the adolescent as well as answering any questions and ensuring completion. When CDC recommends that social distancing is no longer necessary, consenting will return to face-to-face process, however the interviewing may be done face to face or via phone as per participant's request.

Participants already enrolled in the study prior to the social distancing requirement will be informed of changes to the protocol with a consent addendum which will be shared with them via telephone or web, depending on modality we are using with that participant.

Non-English-Speaking Subjects

For all aspects of this study, we will defer to language preference of the participants. The explanation of all aspects of the study (forms, procedures, measures and interventions) will all be available in either Spanish or English. Data analytic discussions and all reports will be in English. Back translations, whenever appropriate, will be conducted. Quantitative surveys will be conducted by the bilingual research team and staff in the preferred language of the participants (English or Spanish). We anticipate that survey protocols will be administered in Spanish for parents and English for the adolescents. Trained coders will transcribe interviews and focus groups in the language in which they were conducted. Data collected in Spanish will be coded using the codebook described below. We will construct the instrument in Spanish and will analyze the transcripts from each session in the original language to avoid second and third order level analysis. The HoMBRES de Familia Research Project will communicate with the male Latino farmworker population in a language that speaks to them—from a cultural and social perspective.

***Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research* involves deception)**

- **NA**

Cognitively Impaired Adults

- NA

Adults Unable to Consent

- NA

31) Process to Document Consent in Writing

We are requesting a waiver of signed consent/assent for Aim 1 as the procedures are of negligible risk and signing forms can be anxiety-producing in this population due to uncertain immigration legal status.

Written approval to the consent/assent will be collected for Aim 2, except for the modification described above for purpose of COVID-19 social distancing. After the study is explained and the participant verbally indicates that he understands, participants will provide written approval and date 2 copies of the consent or assent (youth) form. The research staff or interviewer will co- sign the forms. The participant will be given one copy of the signed consent form for his records, and the second copy will be stored in a locked cabinet at FIU offices.

32) Drugs or Devices

NA