“Preventing HIV Risk Behaviors among Hispanic Adolescents”

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A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention requests approval for a new data collection called “Preventing HIV Risk Behaviors among Hispanic Adolescents” for 3 years.

Background

This project is one of the group of 8 studies within the Minority HIV/AIDS Research Initiative (MARI), which seeks to support junior investigators who are doing HIV/AIDS research in disproportionately impacted African American and Hispanic communities in the United States. The 8 MARI projects are: 1) “Evaluation of Pharmacy Syringe Access Linked to HIV Testing in Black and Hispanic Intravenous Drug Users”(OMB Control number 0920-0837, Expiration Date: 1/31/2013, 2) “Preventing HIV Risk Behaviors among Hispanic Adolescents”, 3) “Family and Cultural Impact on STD and HIV Risk Among Latino and African-American Youth”, 4) “Exploring HIV Prevention Communication among Black Men who have Sex with Men in NYC”, 5) Sexual Risk Taking Among Young Black Men who have Sex with Men: Exploring the Social and Situational Contexts of HIV Risk, Prevention and Treatment(Brothers Connect), 6) “Promoting HIV Testing among Low-Income Heterosexual Young Adult Black Men” (The Beats Project), 7) Empowering Latinas to Lash out Against AIDS (ELLAS), 8) HIV Testing Factors among Rural Black Men (HITFARM).

This request is for *Familias Unidas,* a Hispanic-specific, parent/primary caregiver centered intervention that asserts that parental involvement, positive parenting, parent-adolescent communication, and family support are essential to promoting positive adolescent development and preventing substance use and unsafe sex. Consistent with research literature Familias Unidas considers adults who are not biological parents of childen, but who perform primary caregiving functions for children as parents (e.g. aunts, uncles, grandparents). *Familias Unidas* is delivered through parent/primary caregiver-centered, multi-parent/primary caregiver groups that place parents/primary caregivers in the change agent role through an individual family visit and parent/primary caregiver-adolescent homework assignments. Pantin et al(2003) described the *Familias Unidas* model to be as efficacious in increasing family functioning,

relative to a no-intervention control condition. Prado et al (2007) found *Familias Unidas* to be efficacious in preventing drug use and unsafe sexual behavior, relative to two attention control conditions.

This data collection has 3 objectives: 1) to develop a manual for a one-and-a-half-month streamlined version of Familias Unidas; 2) to evaluate the efficacy of the *Familias Unidas* Program on improving intermediary parenting/caregiving processes (e.g. parental communication, family relationships) that influence families' ability to engage in HIV prevention activities; 3) to evaluate the efficacy of this streamlined *Familias Unidas* program in preventing drug use and unprotected sexual behavior, relative to a standard community practice control condition. Participants' drug use and sexual behavior will be evaluated at 4 months post-intervention, 12 months post-intervention and 24 months post-intervention and will be used to determine intervention efficacy.

This request is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1). This request is not related to the ARRA.

Privacy Impact Assessment

The Principal Investigator, Project Coordinator, and Data Manager will be the only staff members with access to participant information. Participant information such as names, addresses and home telephone numbers and the name and contact information of three people who will always know where participants can be reached will be kept in a secure location at University of Miami in a locked file cabinet and in password protected files. This information will not be transmitted to CDC. In addition, items of information collected through computerized surveys will be stored in password protected files. None of the data collected will contain participant names. The only link to the participants' names will be the consent forms. All records on active participants will be filed in locked file cabinets in the office of the Principal Investigator and will be filed numerically by case number, with no names attached to the database. All data entered into the computerized database will be identifiable by subject code number only. Access to the database and data files will be limited to the Principal Investigator, project coordinator and Data Manager. A master sheet with individual names and their respective code numbers will be kept in a locked file that can be accessed only by the University of Miami staff including, the Principal Investigator,

Project Coordinator and Data Manager. No CDC staff members will be able to access this information. Hence, only the University of Miami staff members will have the keys to the file cabinets and the passwords to the password protected files. The participant information will be destroyed immediately after the participant's contribution to the project has ended.

Overview of the data collection system

The respondents for this study will be Latino adolescents and their parents/primary caregivers. In order to make sure the study meets its target number of respondents, recruitment will be conducted at two Miami-Dade County public high schools. Recruitment letters will be sent to all 9th grade parents/primary caregivers from each of the two high school principals stating that the University of Miami is conducting a study to prevent substance use and HIV risks in Hispanic youth. Parents/primary caregivers will be asked to return the signed letter (with a contact phone number or contact address) to their youth's homeroom teacher indicating whether or not they are interested in learning more about the study. Teachers will keep the signed letters in a locked drawer in their classroom desk until the facilitators come and collect them. The homeroom teacher typically has access to contact information for the students given they are a key contact for the student at the school. Those parents/primary caregivers indicating that they are interested in learning more about the study will be contacted by one of the study's facilitators. The facilitators will then explain the study to the parent/primary caregiver over the phone and set up an initial appointment to meet with the parent/primary caregiver and the target youth. During this initial meeting, the facilitator will screen both the parent/primary caregiver and the youth for eligibility. To avoid potential coercion, parents/primary caregivers and youth will be screened for inclusion/exclusion criteria separately (i.e. in a different office) by the facilitator. If a youth refuses to participate in the study, the facilitator will not tell the parent/primary caregiver that their son/daughter refused to participate. Instead, the facilitator will tell the parent/primary caregiver that the family is not eligible to participate in the study. If a family meets the eligibility criteria, they will be given an informed consent (parents/primary caregivers) and an informed assent (youth). It is anticipated that screening approximately 400 Hispanic immigrant adolescent-parent/primary caregiver dyads from immigrant families would yield the needed sample of 240 dyads to implement the study(for a total of 480 participants).

The 480 eligible participants (240 adolescents and 240 parents/primary caregiver) will be randomized into conditions: The experimental condition which will receive the *Familias Unidas* intervention and the control condition that only receives standard information about HIV from the high schools. The families will be matched and randomized based on criteria of their participating child: gender, birth status (whether they were born in the US or abroad) and risk status for sexual behavior and drug use(e.g. whether or not they have ever engaged in drug use). Over the course of seven weeks, the parents/primary caregivers in the experimental group will receive five group sessions related to improving family functioning as well as decreasing substance use and unsafe sexual behaviors. Both the adolescents and their parents/primary caregivers in this group will receive one family session focusing on improving family communication. Families in this group will also receive three parent/primary caregiver-adolescent homework activities related to the group topics.

Parent/Caregiver and adolescent participants will complete a computerized questionnaire a total of 4 times during the course of the 2-year study: at baseline and at 4 months post-intervention, 12 months post-intervention, and 24 months post-intervention. All adolescent self-report measures will be administered via the Audio Computer Assisted Interviewer Program (A-CASI) in conjunction with direct entry onto a laptop, and all parent/primary caregiver self-report measures will be administered using the A-CASI method in conjunction with touch-screen technology.

Participants in the control condition will only receive the school based HIV risk reduction intervention provided by the Miami-Dade County Public School system to all high school students. The Miami-Dade County Public School system mandates that all high school students receive at least 5 lessons (55 minutes each) per year on HIV prevention. Over the 24 months of the proposed study, the youth will have received 10 sessions on HIV prevention from their schools. They will also receive questionnaires a total of 4 times at baseline, 4 months post-intervention, 12 months post-intervention and 24 months post-intervention.

Items of Information to be collected

The items of information that will be collected include basic demographic information such as age, sex, gender and country of

origin from both parent/primary caregiver and adolescent participants. Parent/primary caregiver-adolescent communication, family support, parental/primary caregiver-adolescent involvement, and parental/primary caregiver-adolescent monitoring of peers will be measured on a "family functioning" scale, which will measure the degree to which the family functions cohesively. There are several other areas that will be measured as separate scales, including level of acculturation (the degree to which an individual from a racial and ethnic group's attitudes and beliefs assimilated to the mainstream culture), adolescent identity, adolescent behavior problems, and school context (school environment). Social cognitive processes such as attitudes, intentions and beliefs towards using drugs and having sex will be measured on a "social cognitive mechanisms" scale, a scale which measures interactions of multiple underlying causal mechanisms. Lifetime and current substance use, having had unprotected sex, and drug use before sex will be used as measures of "adolescent substance use" and "adolescent HIV risk behaviors" scales, respectively.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age.
There will be no websites or internet content directed at children under the age of 13.

2. Purpose of Use of the Information Collection

The information to be collected contributes to the mission of CDC, the Division of HIV/AIDS Prevention and the Division of HIV/AIDS Prevention's Epidemiology Branch. This information collection is consistent with CDC's Mission of "Collaborating to create the expertise, information, and tools that people and communities need to protect their health." Specifically, this project is consistent with CDC's mission to study strategies to prevent HIV/AIDS. This project is also consistent with the Division of HIV/AIDS Prevention (DHAP) mission "to provide national leadership and support for HIV epidemiologic research and for prevention research and the development, implementation, and evaluation of evidence-based HIV prevention programs." Finally, the project is consistent with the mission of DHAP's Epidemiology Branch to "conduct biomedical and behavioral epidemiologic research to reduce HIV infection and disease progression."

This program is funded through the Minority AIDS Research Initiative from the Epidemiology Branch of the Division of HIV/AIDS Prevention of Centers for Disease Control and

Prevention for four years, starting on October 1, 2007 and concluding on September 30, 2011.

Researchers at the University of Miami will implement the proposed intervention and will conduct all data collection. The data collected will be used to determine the effectiveness of a shortened version (2 month) of a previously tested intervention designed to reduce HIV related risk behaviors of Hispanic youth using parent/primary caregiver-communication. The intervention is designed to address behaviors and determinants of HIV transmission and disease progression among Hispanic adolescents who have HIV-related risk behaviors or who live in areas of high HIV incidence. In order to evaluate the effectiveness of the intervention, data will be collected at four intervals baseline, 4 months post- intervention, 12 months post-intervention and 24 months post-intervention. The information collected in the proposed data collection is the minimum amount of information needed to determine intervention efficacy.

The study may help aid CDC's mission to reduce HIV/AIDS by: (1)increasing the number of behavior prevention interventions proven effective for Hispanic adolescents, (2) increasing the number of Hispanic adolescents who consistently engage in behaviors that reduce risk for acquiring HIV and (3) decreasing the number of Hispanic adolescents who use injection drugs. It is imperative for CDC to have more culturally based HIV prevention interventions to combat the emerging epidemic among Hispanics.

If this information is not collected, CDC will be unable to determine whether or not this previously tested intervention is effective in a shortened format. It is important that CDC increase the number of effective short interventions (2 month or less) in its portfolio of interventions because of the difficulties that can arise when implementing longer interventions (e.g. session attendance). This intervention, if effective, will also increase CDC's portfolio of effective HIV prevention interventions for Hispanic and Spanish-speaking populations.

Privacy Impact Assessment Information

This information is being collected in order to inform further development and implementation of a family-based behavior intervention program for Hispanic youth. These programs will be focused on reducing disparities in HIV infection between Hispanics and non-Hispanic white populations.

Similar to other behavioral intervention research, the findings of this study will be disseminated through peer-reviewed journals, departmental reports, abstracts, presentations at national and international scientific and public health meetings, and local media outlets (i.e. Miami-Dade Spanish newspapers). The Miami-Dade Public School Board, our local community partners, will help in disseminating the findings to the local community. Dissemination of findings and other products is intended to add to the public health knowledge base. There is no intent for others to apply these findings outside of the original, Hispanic target groups. CDC, specifically the Division of HIV/AIDS Prevention, has other programs that examine the applicability and effectiveness of adapting programs to new target populations, as appropriate.

Information in Identifiable Form (IIF) will be collected by the research staff from the University of Miami to conduct the study. IIF will be used by research staff to contact study participants to schedule intervention sessions and data collection. This information will be collected and the loss of confidentiality could potentially result in the harm to the participants. In order to safeguard the IIF collected the principal investigator has requested and has received a Certificate of Confidentiality (COC) from CDC to protect the privacy of research subjects by protecting the investigators and institutions from being compelled to release information that could be used to identify subjects with the research project (See Attachment 7). The study is bound to adhere to the procedures outlined in the COC which are designed to safeguard this information and to ensure that this information will be keep private and safe. In order to protect the participants' identities, once they are enrolled they will be assigned a code number that will be used in lieu of a name for data collection activities. A master sheet with individual names and their respective code numbers will be kept in a locked file that can be accessed only by the University of Miami staff including, the Principal Investigator, Project Coordinator and Data Manager will have the keys to the file cabinets and the passwords to the password protected files. No IIF will be available to or shared with the CDC. All analyses of the data will take place at the University of Miami.

Participants will be advised that the information will not be shared beyond what was revealed to them in their consent form. Local implementers will ensure that there will not be any perception of coercion.

3. Use of Improved Information Technology and Burden Reduction

All of the information will be collected using an A-CASI(Audio Computer Assisted Structured Interview) system at each data collection (baseline, 4 month, 12 months and 24 months).

All adolescent self-report measures will be administered via the Audio Computer Assisted Interviewer Program in conjunction with direct entry onto a laptop. All parent/primary caregiver self-report measures will be administered using the A-CASI method in conjunction with touch-screen technology. The "Parent/Primary Caregiver Assessment Battery" (Attachment 3b and "Adolescent Assessment Battery" (Attachment 3c) will be administered to parents/primary caregivers and adolescent participants, respectively, by study staff. The A-CASI method allows information to be stored as it is collected.

The use of an A-CASI system will decrease the time needed to complete the assessments and thereby will reduce the burden on the public. Data collection for the study will be 100% electronic; no paper forms will be used for data collection. During assessments, data will be entered directly onto laptop computers by study participants and downloaded onto a secure server weekly.

4. Efforts to Identify Duplication and Use of Similar Information

There are currently no data related to whether or how a streamlined seven-week version of *Familias Unidas* will be effective in preventing drug use and unsafe sex among Hispanic youth. There is no similar information available about Hispanic youth in Miami. This information collection about the efficacy of a HIV prevention intervention does not duplicate any other effort.

5. Impact on Small Business or Other Small Entities

This information collection will not have an impact on small businesses, but will have a slight impact on the two High Schools from which the study will recruit from, which are small entities. The recruitment procedures that will take place through the schools do not constitute additional burden as they

are similar to the recruitment that takes place at the schools for other school-related programs.

6. Consequences of Collecting the Information Less Frequently

There is no routine data collection, except for the scheduled data collection time points at baseline, 4, 12 and 24 months. Based on previous research conducted by the principal investigator, these data collection intervals are the minimum necessary to demonstrate the effectiveness of the intervention on the desired risk outcomes (Pantin et. al, 2003; Prado et. al, 2007). If the information is collected less frequently, it will be difficult to determine the effect time of the intervention.

7. Special Circumstances relating to the Guidelines of 5 CFR 1320.5

The request fully complies with the guidelines of 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Federal Register Notice was published in the Federal Register on January 28, 2010, vol. 75, No. 18, pp. 4567-4568 see attachment (See Attachment 2).

1 comment was received on 02/19/2009 from Jean Public. (See attachment 2a)

B. This protocol was developed collaboratively between The University of Miami and the Centers for Disease Control and Prevention. The persons consulted outside of the CDC are:

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9. Explanation of Any Payment or Gift to Respondents

All families will be offered a token of appreciation of $40, $45, $50 for completing assessments, and $55 for completing the baseline, post-intervention and the two follow-up assessments, respectively. All tokens will be given to the parent/primary caregiver. Families who complete all four assessments could be offered up to $190 for the duration of the study, a 24-month period. This token is being offered to justify the hours spent completing assessments and to maximize retention in the follow-up sessions. Maximizing the retention in follow-up assessments will enhance the quality of the study and results. Through previously conducted research with this target population and in the original version of this intervention, the investigators have determined that this level of token is the minimum amount acceptable to the target population to retain them in the study (Prado et al., 2007).

While tokens of appreciation will be utilized for the assessments in this study, there is no intention to continue their use if this intervention is proven to be effective and widely adopted, disseminated and continually evaluated among Latino families.

10. Assurance of Confidentiality Provided to Respondents

Privacy Impact Assessment Information

A. This submission has been reviewed by ICRO, who determined that the Privacy Act applies to this request and the applicable System of Records notice is 09-20-0160.

The protocol #5466, titled “Preventing HIV Risk Behaviors among Hispanic Adolescents”, was determined by the NCHHSTP Associate Director of Science office to have human subject involvement, but the CDC involvement does not constitute “engagement in human subject research” on August 26, 2009. As a result, this protocol does not require CDC IRB approval only local IRB which occurred on April 7, 2010 and will expire on April 6, 2011(Attachment 6a).

Measure will be taken to ensure that the participants are made aware the information they provide will only be available to project research staff.

B. Several measures will be taken to secure the information collected. Signed Letters indicating parents'/primary caregivers' interest in the program and their family contact information will be collected by homeroom teachers who will keep that information in a locked desk until a member of the research staff comes to collect them. The research staff will collect them and place them in a locked file cabinet at the University of Miami that can only be access by project staff.

All data assessment data entered into the computerized database will be identifiable by subject code number only. Access to the database and data files will be limited to the Principal Investigator, Project Coordinator and Data Manager. A master sheet with individual names and their respective code numbers will be kept in a locked file that can be accessed only by the University of Miami staff including, the Principal Investigator, Project Coordinator and Data Manager will have the keys to the file cabinets and the passwords to the password protected files. The master sheet that links the individuals' names and their respective response code numbers will be kept for up to five years after the end of the study. After five years the sheet will be destroyed and there will be no information linking the participants' identifying information with their response data.

The "Parent/Primary Caregiver Assessment Battery" (Attachment 3b-English Language and Attachment 3d-Spanish Language) and "Adolescent Assessment Battery" (Attachment 3c-English Language and Attachment 3e-Spanish Language) administered via the Audio Computer Assisted Interviewer Program will be stored as it is collected.

ACASI data will be downloaded weekly and stored on a secure, password protected computer. Procedures to ensure quality control in the collection, verification, and documentation of data have been established and will be conducted by a Data Analyst/Programmer on the study staff in consultation with our Senior Programming Consultant.

Overall, access to the database and data files will be limited to the Principal Investigator, Project Coordinator and Data Manager. Passwords are used to restrict entry into the database. Personally identifiable information will be coded such that no participants can be identified. All data entered into the computerized database will be identifiable by subject

code number only. No one other than the Principal Investigator, the Project Coordinator, and the *Familias Unidas* facilitators will have access to records identifying subjects' names at any time. However, the *Familias Unidas* facilitators will not have access to the data collected as part of the assessment. Hence, only the Principal Investigator and the Project Coordinator (under the supervision of the Principal Investigator) will have access to both the participant's identifying information and their assessment data.

The study has acquired a Certificate of Confidentiality from CDC (Attachment 7). A Certificate of Confidentiality protects personally identifiable information about subjects in the research project while the Certificate is in effect. Under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) the Certificate of Confidentiality protects all information identifiable to any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during any time the Certificate is in effect. The protection afforded by the Certificate is permanent. All personally identifiable information maintained about participants in the project while the Certificate is in effect is protected in perpetuity.

C. Participants provide written informed consent and assent to participate in the study in English and Spanish (see Attachments 4a-4d). The consent form will be read aloud to the respondents in order to enhance their comprehension. The consent forms provide the participants with an explanation as to who has access to the data, how the data will be shared and a telephone number to call in case they have questions about the study.

D. The consent and assent forms clearly indicate that he/she is voluntarily joining the study and there are no mandatory requirements that they join the study. They are also free to leave the study at any time.

11. Justification for Sensitive Questions

Adolescent and Parent/Primary Caregiver participants will be asked questions of sensitive nature. During screening for eligibility, respondents will be asked questions about their age, race/ethnicity, gender, whether or not their parent/primary caregiver is an immigrant, and prior psychiatric hospitalization (Attachment 3a).

These questions are necessary to determine eligibility for the study. Those who have been hospitalized with the psychiatric disorders are excluded because their hospitalization will influence the other aspects of family functioning and would require the development of a separate intervention.

Parents/Primary caregivers of the adolescents will be assessed using the "Parent/Primary Caregiver Assessment Battery" (Attachment 3b and 3d). The "Parent/Primary Caregiver Assessment Battery" will include questions pertaining to family functioning (parent/primary caregiver-child communication, family support, parental involvement parental/primary caregiver monitoring of peers), acculturation, social support, parental/primary caregiver substance abuse and parental stress (see Attachments 3b and 3d). Collecting this information is necessary in order to characterize the population and assess the degree to which these indicators contribute to adolescent risk behaviors. Knowledge of these factors will help in developing future culturally sensitive interventions for Hispanic communities.

Adolescents will be assessed using the "Adolescent Assessment Battery" (Attachments 3c and 3e). The "Adolescent Assessment Batter" will include questions pertaining to family functioning (parent child communication, family support, parental involvement parental monitoring of peers), acculturation, substance use, sexual and other HIV risk behaviors, as well as attitudes about these behaviors are needed to evaluate if and how these behaviors evolve over time (see Attachments 3c and 3e). Collecting this information is necessary in order to characterize the population and assess the degree to which these indicators contribute to adolescent risk behaviors. Knowledge of these factors will aid in the development of future culturally sensitive interventions for Hispanic communities.

12. Estimates of Annualized Burden Hours and Costs

A. There are two types of respondents, Hispanic adolescents and their parents/primary caregivers. Study staff will recruit potential Hispanic families for participation via letters and phone calls in English and Spanish (See Attachments 5c and 5e). During this phone call, the staff will answer explain the purpose of the study, answer any questions and set up a time for the families to be screened. It is estimated that each call will last approximately 9 minutes. Study staff will screen approximately 400 dyads (=800 persons) of Hispanic adolescents and their parents/primary caregivers from two Miami-Dade County

public high schools during the first year. The 400 dyads will take part in a 3-minute screening interview to assess study eligibility. Of the total number screened for eligibility approximately 240 adolescents and their parents/primary caregivers (total of 480 participants) are expected to participate in the study. The number of expected participants is based on the eligibility of parent/primary caregiver-adolescent dyads from previous studies the principal investigator has conducted and the number of participants needed to have enough statistical power to produce moderate effect size (Pantin, et al., 2003; Prado et al., 2007ß). Assessment data will be collected 4 times over the course of the study. During the first year of the project participants will be assessed at recruitment (baseline) and 4 months post-intervention. During the second year of the project, participants will be assessed at 12 months post-intervention and 24 months post-intervention.

Adolescents will spend approximately 60 minutes completing the assessment at each data collection for a total of 2 hours annually. Parents/Primary caregivers of adolescents will spend approximately 45 minutes completing the assessment at each data collection for a total of 1.5 hours annually. The average time necessary to complete the assessments was estimated based on the investigator's prior prevention research using identical questionnaires (Pantin et al., 2003; Prado et al., 2007).

Table 12.A Estimate of Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Respondent (in hours)	Total Burden (in hours)
Parents/Primary Caregiver of Hispanic Adolescents	Recruitment Phone Script	400	1	9/60	60
Hispanic Adolescents and Parents/Primary Caregiver	Parent/ Primary Caregiver and Adolescent Screening Form	800	1	3/60	40
Parents/Primary Caregiver of Hispanic Adolescents	Parent/ Primary Caregiver Assessment Battery	240	2	45/60	360
Hispanic Adolescents	Adolescent Assessment Battery	240	2	1	480

Total	**940**

B. Annualized cost to respondents for the burden hours is provided in Exhibit A.12.B. The estimates of hourly wages were obtained from the Department of labor[1] in 2009. The hourly wage rate calculation for screening includes even burden between adolescents and adults, so average of the hourly rate for the two groups was used.

Exhibit A.12. B: Estimated Annualized Burden Costs

Type of Respondent	Total Burden hours	Hourly Wage Rate	Total Respondent Cost
Parents/primary Caregivers of Hispanic Adolescents-Family Recruitment Script	60	$20.23	$1,213.80
Hispanic Adolescents and Parents/Primary Caregivers–Screening	40	$13.04	$521.60
Parents/Primary Caregivers of Hispanic Adolescents-Assessment Battery	360	$20.23	$7282.80
Total	940		$11,826.20

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no costs to respondents other than their time.

[1] CDC researchers commonly cite the Bureau of Labor Statistics Wage Data (http://www.bls.gov/bls/wages.htm)

14. Annualized Cost to the Federal Government

This project is funded through a Cooperative Agreement to the University of Miami (PS07-003/U01 PS 000671) for four years. The cost of the project for 4 years is estimated to be $1,199,022.

Exhibit A.14: Estimates of Annualized Costs to the Federal Government.

Expense Type	**Expense Explanation**	**Annual Costs (dollars)**
Direct Costs to the Federal Government	CDC Project Officer/Co-Principal Investigator (GS-13, .25 FTE)	$21,375
Operational	Equipment, travel, support staff, printing, etc	$2,692 for travel
Contractor and Other Expenses	Cooperative Agreement to The University of Miami	$271,527
	Subtotal, Direct Costs to the Government	$271,527 (Only direct costs)
	TOTAL COST TO THE GOVERNMENT	$295,594 (includes direct and indirect costs)

Salary estimates were obtained from OPM salary scale (http://www.opm.gov) and the United States Public Health Service Commissioned Corps Website (http://dcp.psc.gov).

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Exhibit A.16: Project Time Schedule

Activity	Time Schedule
Recruit and enroll study participants	1 month after OMB approval
Baseline assessment	1-2 months after OMB approval
Familias Unidas intervention sessions	2-4 months after OMB approval
First post baseline collection	4 months post-intervention
Annual assessment: Data collection and analysis	12 months post-intervention
End of project assessment	24 months post-intervention

17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exception is requested.

18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions

No exception is requested.