2018 Congenital Syphilis Study

Generic Information Collection Request under Formative Research and Tool Development OMB #0920-0840

Section A: Supporting Statement

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- **Goals of the study:** The goals of this formative qualitative research study are to: 1) Assess prenatal care provider knowledge, attitudes, and practices around congenital syphilis and its prevention 2) Assess how prenatal care providers and high-risk pregnant women learn about congenital syphilis and where they seek information 3) Evaluate high-risk pregnant women's knowledge of STDs and syphilis, patient decision making around whether to seek prenatal care and patient use of prevention behaviors during pregnancy.
- **Intended use:** Findings from this qualitative assessment will be used to seek recommendations for improving outreach to women at highest risk for syphilis infection/transmission and generate ideas for culturally appropriate ways to engage high-risk pregnant women in the use of prenatal care services.

- **Methods to be used to collect data:** Data will be collected from up to 20 prenatal care providers through semi-structured, in-depth qualitative phone interviews and up to 80 high-risk pregnant women through in-person focus groups.

- **The subpopulation to be studied:** Data will be collected from up to 20 prenatal care providers working in Kern County, California and Baton Rouge County, Louisiana. Data will also be conducted for up to 8 focus groups with high-risk pregnant women in Kern County, California and Baton Rouge County, Louisiana.

- **How data will be analyzed:** Interview and focus group notes will be transcribed and imported into QSR NVivo V10 or analyzed through identification of recurrent themes following Crabtree and Miller's 5 step interpretive process.

Supporting Statement A.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC) Division of STD Prevention, (DSTDP) requests OMB approval for a qualitative extramural research study entitled, "Addressing the Rise of Congenital Syphilis: Working toward Setting-specific Solutions among High-Risk Pregnant Women" in Kern County, California and Baton Rouge, Louisiana under "Formative Research and Tool Development" Generic Clearance OMB #0920-0840 (expires 1/31/2019). CDC will sponsor this data collection activity. Data collection will be carried out by CDC's cooperative agreement partner, March of Dimes Foundation (MOD), in conjunction with its subcontracting local partners, University of California at San Diego and Tulane University.

Congenital syphilis has become an alarming problem that urgently requires awareness, attention, and action. Data from the most recent CDC STD Surveillance Report found that the number of CS cases spiked for the fourth year in a row. From 2015-2016 alone, there were a total of 628 cases – a rise of nearly 30% over the previous year. Thirty-seven states reported at least one case of CS; however, the majority of cases are concentrated in just a few areas. Evidence from CDC suggests that cases of congenital syphilis are concentrated geographically and certain population groups are disproportionately affected. Congenital syphilis can lead to fetal loss, infant death, or a life of major health problems. Congenital syphilis (also referred to as Mother-to-child transmission (MTCT) of syphilis) is completely preventable through effective antenatal screening, and treatment of infected pregnant women.

The spike in congenital syphilis cases in the United States between 2012 and 2015 represents an urgent public health problem. The proposed study will expand on what is already known about the epidemiology of the incidence in distinct settings and population groups in the United States, and lessen the existing gap in knowledge on how to effectively communicate with patients at highest risk for syphilis infection/transmission and the health care providers who can offer prevention and treatment services. There is a unique opportunity to inform and improve existing syphilis prevention efforts by engaging with pregnant women (including those most hard to reach) and prenatal providers in two of the highest-morbidity regions in the country. The results from this study will not only inform prevention efforts in Kern and East Baton Rouge - we believe they will be generalizable to other high-morbidity jurisdictions through the United States.

Given that MTCT of syphilis is fully preventable, the recent spike in its incidence suggests that unknown and/or more nuanced, complex determinants of its occurrence remain uncovered or insufficiently addressed. Urgent action is needed to increase our understanding of the reason(s) behind the recent surge in syphilis cases so effective solutions can be put in place. There exists a substantial body of practical knowledge and experiential theory on why many opportunities are missed along each step of a continuum of prevention, detection and treatment for syphilis among pregnant women. Concrete, empirical evidence is critically needed to confirm where gaps exist in knowledge, attitudes, decision-making practices and behaviors contributing to the resurgence in syphilis transmission. This evidence is needed to improve/modify congenital syphilis prevention efforts it can be mitigated and eradicated.

2. Purpose and Use of the Information Collection

The proposed qualitative study will assess the knowledge, attitudes, factors that influence decision-making and behavioral practices surrounding sexually transmitted diseases (STDs) in general, and congenital syphilis in particular, among high-risk pregnant women and prenatal care providers in two of the most hard-hit, high-morbidity counties in the United States (U.S.): Kern County, California (CA) and East Baton Rouge Parish (county), Louisiana (LA). Please **(Attachment 7)** for the complete research plan that identifies the aims of the project.

The proposed two-site study will involve the design, implementation, and analysis of two qualitative assessment components in Kern County, CA and East Baton Rouge Parish, LA. Through in-depth interviews (10 per site) with a variety of prenatal care providers and focus group discussions (4 per site) with high-risk pregnant women we will collect rich qualitative data reflecting the complexities and setting-specific details on local providers' and women's levels of knowledge, attitudes, and practices surrounding congenital syphilis and its prevention.

Recruitment procedures for prenatal care providers IN KERN COUNTY:

During the introductory meetings to be conducted at each site, the investigators will identify (through direct inquiry and collaboration/communication with the site contact person at each location) obstetrical providers whose clinics care for a high volume of high risk women. Providers from each of the four sites will then be asked to recommend at least one antenatal provider from their respective clinics to participate in an in-depth interview. A comprehensive list of names and contact information (including

cell phone number, work number, email address) for potential prenatal care provider participants will be generated. Study recruiters will use this information to follow-up with each individual through a phone call and/or email to re-invite the potential participant to answer any questions about the study and invite him/her to enroll. If he/she expresses interest in participation, the study recruiter will set up a specific interview appointment time and location.

Recruitment of prenatal providers will also be done through distribution of the participant information sheets. People who attend these meetings will be asked to share this information with colleagues who were unable to attend. Interested, prospective participants can use the contact details provided on the information sheet to get in touch with the study investigators.

Another method for recruitment will include using posters (placed in the specific locations where services are provided for pregnant women) in each of the four sites. Posters will include details of the study, eligibility criteria for prenatal providers, information about tokens of appreciation and contact details for the research team. If prospective participants are interested in discussing the study further or participating, they can contact the investigators directly using contact details on the poster.

Recruitment of high risk pregnant women in Kern County:

Recruitment procedures in Kern County will be the same across sites and are outlined below, separated by recruitment method.

Study Posters: The investigators will work with a specified local contact person at each location to compile a list of clinics or departments and/or providers that provide services or engage with high-risk pregnant women in Kern County. These local contacts will distribute study flyers and posters, which will provide information about the study, as well as contact information for the study team for those who are interested in participating. Posters/flyers will be informative but brief, including information about the purpose of the study; format of data collection (i.e., focus groups); eligibility for participation; details on tokens of appreciation; and contact details for the study team. Potential participants interested in talking to investigators about the study and/or wanting to enroll can call the investigators, as directed on the flyer. Additionally, in order to reach women who may not have been exposed to these advertisements, study coordinators will hang flyers in other public places, such as large grocery stores

that allow flyers, the Department of Human Services, and childcare centers (such as the YMCA) throughout Kern County. Recruitment through study posters will be ongoing, until the overall sample size is reached.

Antenatal care providers: Study researchers will ask all willing antenatal care providers at the recruitment sites to mention the study to patients who they believe may be eligible. Specific names of providers will be identified during the first few months of study preparations, to ensure that they can be trained and ready to identify patients by the time recruitment begins. Training for antenatal care providers is expected to be completed during months three and four of the grant, with participant recruitment occurring during months four through six. Providers will be trained on study procedures, identification of potentially eligible patients, and ways to refer them to the study. Investigators will also ensure that all clients receiving services from antenatal care providers are given a copy of the study flyer and a "Participant Information Sheet" during consultations. The information sheet will contain a more detailed explanation of the study, as well as contact information for the UC San Diego research team.

Snowball Sampling: Participants will also be recruited via snowball sampling, whereby participants who are recruited/informed about the study will be asked to pass on study contact details and a participant information sheet or flyer to pregnant women they know who fulfill the inclusion criteria. This way, pregnant women receiving services at any of the recruitment sites can talk about the study with friends and family and participants can be recruited as a result of word of mouth.

On-site Liaisons: At each site, 1-2 staff members will be identified and trained to serve as a liaison between the recruitment site and the study team. These staff members will be informed about the study, its purpose, the type of data collection to be done (FGDs), the characteristics of the participants to be recruited (i.e., eligibility criteria) and the study team contact details. Pregnant women will be informed through flyers and antenatal care providers that an alternative to directly contacting the investigators is to leave their information with a liaison at the clinic, who will forward this information to a research team member, and a researcher will contact the interested, potential participant by phone. Women's names and numbers obtained at by liaisons will only be used for recruitment and will not be stored or shared with anyone. For confidentiality purposes, liaisons will not ask women to identify themselves by their last name, and will only collect first names. This information will be recorded in a password protected document and will be emailed through an encrypted and secure email service. This

information will not be made available to anyone outside the research team. After contacting the participant, their information will be deleted from the document. Liaisons will also share flyers and answer questions from potential participants, as approved by the local contact.
All recruitment and data collection activities will be conducted by the locally appointed qualitative research team.

Recruitment procedures for prenatal care providers in east Baton Rouge Parish:
During introductory meetings to be conducted at each site, the investigators will identify (through direct inquiry and collaboration/communication with the site contact person at each location) obstetrical providers whose clinics care for a high volume of high risk women. Providers from each of the three sites will then be asked to recommend at least one antenatal provider from their respective clinics to participate in an in-depth interview. A comprehensive list of names and contact information (including cell phone number, work number, email address) for potential prenatal care provider participants will be generated. Study recruiters will use this information to follow-up with each individual through a phone call and/or email to re-invite the potential participant to answer any questions about the study and invite him/her to enroll. If he/she expresses interest in participation, the study recruiter will set up a specific interview appointment time and location.

Recruitment of prenatal providers will also be done through distribution of the participant information sheets. People who attend these meetings will be asked to share this information with colleagues who were unable to attend. Interested, prospective participants can use the contact details provided on the information sheet to get in touch with the study investigators.

Another method for recruitment will include using posters (placed in the specific locations where services are provided for pregnant women) in each of the three sites. Posters will include details of the study, eligibility criteria for prenatal providers and contact details for the research team. If prospective participants are interested in discussing the study further or participating, they can contact the investigators directly using contact details on the poster.

Recruitment of high risk pregnant women in east Baton Rouge Parish:
Woman's Hospital: The investigators will work with identified contact persons to obtain/generate a list of antenatal and other medical providers and obstetrical clinics that provide prenatal care services for a

high volume of high-risk women at Woman's Hospital. Study posters/flyers will be distributed and displayed in recommended clinic sites so patients are exposed to these materials during routine prenatal care visits. Posters/flyers will be informative but brief, including information about the purpose of the study; format of data collection (i.e., focus groups); eligibility for participation; details on tokens of appreciation; and contact details for the study team. Potential participants interested in talking to investigators about the study and/or enroll can call the investigators, as directed on the flyer. Recruitment will also be done on specific days when the investigators/study recruiters will spend time at Woman's Hospital, giving out flyers and answering questions from potential participants.

LSU OB/GYN Clinic: Per the same protocol described above for Woman's Hospital, study flyers/posters will be displayed openly throughout the LSU OB/GYN Clinic so patients are highly exposed to the information. Additionally, the investigators will partner with a LSU OB/GYN Clinic's social worker ensure that all clients receiving services from the Clinic's social workers are provided a copy of the study flyer during consultations.

Participants will also be recruited via snowball sampling whereby participants who are recruited/informed about the study by their social worker will be asked to pass on study contact details and a participant information sheet or flyer to pregnant women they know who fulfill the inclusion criteria. This way, pregnant women receiving services at LSU OB/GYN Clinic can talk about the study with friends and family and participants can be recruited as a result of word of mouth.

The investigators will also identify 1-2 clinic staff members to liaise between the recruitment site and the investigative team. These staff members will be informed about the study, its purpose, the type of data collection to be done (FGDs), the characteristics of the participants to be recruited (i.e., eligibility criteria) and the study team contact details. Women receiving services at the LSU OB/GYN Clinic will be informed (through flyers and by the social work staff) that an alternative to directly contacting the investigators is to leave their information with a staff member at the clinic and have a researchers contact them by phone. In this case, the potential participant can leave her first name and phone number with the designated staff member, who will relay the information to the researchers. Women's names and numbers will only be used for recruitment and will not be stored or shared with anyone. This information will be recorded in a password protected document and will be emailed through an encrypted and secure email service. This information will not be made available to anyone outside the

research team. After contacting the participant, their information will be deleted from the document. On specific days, investigators/ recruiters will be available to give out flyers and answer questions from potential participants at LSU OB/GYN Clinic locations.

Family Road Healthy Start: Per the same protocol described above for Woman's Hospital, study flyers/posters will be displayed throughout Healthy Start so patients are exposed to the information. Additionally, case workers who meet individually with pregnant women in the Healthy Start Program will be asked to distribute the study flyers about the study purpose, focus group format, tokens of appreciation, and contact details of research team. Interested participants can reach out directly to the study team.

Participants will also be recruited via snowball sampling whereby participants recruited/informed about the study by their Healthy Start case worker will be asked to pass on study contact details and a participant information sheet or flyer to pregnant women they know who fulfill the inclusion criteria. This way, pregnant women receiving services at Family Road Healthy Start can talk about the study with friends and family and participants can be recruited as a result of word of mouth.

Pregnant women participating in the Healthy Start Program who are interested in the study can also leave their information with a case worker (who will be trained to serve as a liaison between the recruitment site and the study team). The case worker will share this information with the study team and a researcher will contact the potential participant by phone. Women's first names and numbers obtained at the Family Road Health Start location will only be used for recruitment and will not be stored or shared with anyone. For confidentiality purposes, liaisons will not ask women to identify themselves by their last name, and will only collect first names. This information will be recorded in a password protected document and will be emailed through an encrypted and secure email service. This information will not be made available to anyone outside the research team. After contacting the participant, their information will be deleted from the document. On specific days, investigators/ recruiters will be available to give out flyers and answer questions from potential participants at Healthy Start, as approved by a study contact person.

Information collected from providers

Through our study, we aim to learn about current antenatal care practices in regions of the United States with high prevalence of sexually transmitted infections like syphilis. The purpose of this formative study

is to develop guidelines for health care users to effectively communicate with their patients at highest risk for syphilis infection/transmission so as to offer the best prevention and treatment services. During the interview, investigators will ask questions on professional practices related to STD prevention, including syphilis and congenital syphilis. They will also ask questions about any training or guidance providers have received on testing and treatment for syphilis and congenital syphilis and questions about any guidelines or guidance related to testing and treating women for syphilis during pregnancy (**Attachment 5b**).

Information collected from pregnant women

Through our study we aim to learn how we can improve pregnancy care services so as to meet the needs and interests of pregnant women in Kern County/East Baton Rouge Parish. The focus group will provide us with information that can be used to improve pregnancy care in Kern County / East Baton Rouge Parish. We will ask questions about the ways women in these communities get information about their health, overall and during pregnancy, and general health and pregnancy. Each of the questions will not ask participants about their experiences specifically, they will be told that they can contribute to the conversation as much or as little as they want (**Attachment 5d**).

3. Use of Improved Information Technology and Burden Reduction

Staff from UCSD and Tulane will conduct individual phone interviews at a time and location that is convenient to the selected respondents. Telephone interviews will reduce burden on respondents' time and resources from having to travel to a physical location to participate in this data collection, as well decrease study recruitment costs. After asking for and receiving permission from the respondent, UCSD and Tulane will audio-record the interviews and transcribe recordings after the interview. This also limits the burden on the respondent (no additional burden after completing the interview) and allows the interviewer to focus on building and maintaining rapport with the respondent. Focus group discussions among high risk pregnant women will be conducted to complement the in-depth interviews with providers. These focus groups will be located at a time and location that is central to participants. Each focus group discussion will be audio recorded and transcribed when the focus group is completed. Participants will provide written consent prior to the start of the focus group discussion. All discussions will be structured by use of a guide and will last 1-2 hours.

4. Efforts to Identify Duplication and Use of Similar Information

CDC conducted a review of similar studies and determined no other data collection effort has been conducted or has been planned to collect similar information for these populations because this study is

collecting unique information from these specific populations. Therefore, our study requires the collection of this new primary data.

5. Impact on Small Businesses or Other Small Entities

This study will partner with local departments of health (in Kern and East Baton Rouge counties), local hospitals or clinics to facilitate recruitment to aid in recruiting potential respondents by identifying eligible potential respondents through their routine and regularly occurring activities and referring them to the study. The recruitment burden is found in section 12 of this document.

6. Consequences of Collecting the Information Less Frequently

There exists a substantial body of practical knowledge and experiential theory on why many opportunities are missed along each step of a continuum of prevention, detection and treatment for syphilis among pregnant women. Concrete, empirical evidence is critically needed to confirm where gaps exist in knowledge, attitudes, decision-making practices and behaviors contributing to the resurgence in syphilis transmission. If this evaluation were not conducted, it would not be possible to gather the information that is needed to improve/modify congenital syphilis prevention efforts that can be mitigated and eradicated. The length of data collection is 2-4 months and data will only be collected once.

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

This data collection effort does not involve any special circumstances.

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

A 60-Day Federal Register Notice for the generic clearance 0920-0840 was published on 06/25/2015, Vol. 80 No. 122, pages 36540-36542, exp. 01/31/2019.

The following partnering staffs at UCSD and Tulane were consulted for the development of this study. There were no unresolved issues associated with the consultation process.

Jennifer Wagman, PhD, MHS Co-Principal Investigator University of California, San Diego	Emily Harville, PhD, MSPH Co-Principal Investigator Tulane University School of Public Health and

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9. Explanation of Any Payment or Gift to Respondents

Prenatal care providers will receive a $50 token of appreciation in the form of gift card. Focus group participants will receive a $25 token of appreciation also in the form of a gift card. This amount has been previously judged appropriate by UCSD and Tulane Human Research Protection Program. Although there has been some debate on the necessity of offering tokens of appreciation, numerous studies have shown that tokens of appreciation can significantly increase response rates, and the use of modest tokens of appreciation is expected to enhance survey response rates without biasing responses (Abreu & Winters 1999; Shettle 1999). Additionally, offering tokens of appreciation is cost-efficient, decreasing cost to government by reducing the number of contact attempts necessary to gain participation when no token of appreciation is offered (Bricker 2014). All gift cards will be given out at the completion of the interviews and focus groups.

Participating in a 60-120 minute in-depth interview requires a considerable investment of personal time on the part of the prenatal care provider, with the potential for inconvenience to the respondent. They are busy professionals and participating in this study will divert time away from them seeing patients. Pregnant women are frequently juggling multiple priorities, and can best be enticed to participate in focus groups by offering a nominal token of appreciation. Data quality depends on being able to recruit engaged respondents who are willing to spend time and share their perspectives with the interviewer. The study team feels that anything less than $50 for providers and $25 for focus group participants is likely to hamper recruitment and would not be reflective of the level of appreciation warranted by the respondent's contribution to the study aims.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This activity has been assessed for applicability of 5 U.S.C. § 552a, and has determined that the Privacy Act applies to the information collection. Personal identifiable information (PII) is being collected as a result of this CDC funded study. A privacy impact assessment was conducted to ensure the protections of the collected information. (**Attachment 9**). This information collection is covered under the Privacy Act system of records notice (SORN) # 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems. HHS/CDC", which enables the Centers for Disease Control and Prevention (CDC) officials to collect information to better understand disease patterns in the United States, develop programs for prevention and control of health problems, and communicate new knowledge to the health community.

The personal identifiable information (PII); phone numbers, email addresses, and names will only be used for recruitment purposes. For recruitment, potential provider names, phone numbers, and email addresses will be collected in order for recruiters to reach out and recruit providers for the study. The Principal Investigators will collect first name and phone number of pregnant women to screen them as part of the study. They will also collect race/ethnicity and income information as part of the screening process. This data will not be used beyond the screening portion of the project. CDC will not have access to any data. The CDC will not request or receive any PII from the contractors or providers who commonly see the patient responders. CDC will only receive a summary of the interview and focus group findings and summary report. The contact information will only be used for recruitment and will never be tied to the survey/focus group data submitted to the CDC. Respondents will be informed that their responses will be kept private to the extent permitted by the law. All respondents interviewed will be informed that the information collected will not be attributable directly to the respondent and will only be discussed among members of the research team. Terms of the CDC contract authorizing data collection require the contractor to maintain the privacy of all information collected. Accordingly, individuals' data will be kept private and protected to the extent permitted by law.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval:

This study has been reviewed and approved by the UCSD and Tulane Institutional Review Board IRB (**Attachment 6**).

Sensitive Questions:

This study is an initiative aimed to inform the development of strategies to prevent and reduce congenital syphilis. We do not plan to collect any sensitive information from respondents. The principal

investigators have more than 17 years of experience in training staff to conduct confidential and sensitive interviews. We will inform all respondents that they may skip any question or stop participation at any time for any reason.

12. Estimates of Annualized Burden Hours and Costs

The overall burden was calculated per respondent by multiplying the frequency of response by the time to complete each data collection item.

We anticipate that the screener process will take 10 minutes to complete for both providers and pregnant women.

- For the screening of providers (**Attachment 5a**), we expect to screen 30 Prenatal Providers, providing 1 response each taking 10 minutes for each response, for a total of 5 burden hours
- For the screening of pregnant women (**Attachment 5c**), we expect to screen 90 women, providing 1 response each taking 10 minutes for each response, for a total of 15 burden hours.

We anticipate that interviews will take 2 hours to complete for providers and pregnant women.

The in-depth interviews for providers are expected to take an estimated 2 hours. We will complete interviews for up to 20 total prenatal care providers (10 in Kern County and 10 in East Baton Rouge Parish, LA).

- For the in-depth interviews for providers (**Attachment 5b**), participating in the interviews, we expect to interview 20 providers, providing 1 response each taking 2 hours for each response, for a total of 40 burden hours.

The in-depth interviews for pregnant women are expected to consist of up to 8 focus groups with a total of 64-80 participants (up to 10 women/focus group in Kern County and East Baton Rouge Parish, LA).

- For the interviews of pregnant women (**Attachment 5d**), participating in the focus group interviews, we expect to interview 80 women, providing 1 response each taking 2 hours for each response, for a total of 160 burden hours. Therefore, the total estimated burden hours for this activity is 220.

12A. **Estimated Annualized Burden Hours**

Exhibit 12.1: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
Prenatal care providers	Eligibility Screener (Att. 5a)	30	1	10/60	5
Prenatal care providers	Interview Guide (Att 5b)	20	1	2	40
Pregnant women	Eligibility Screener (Att 5c)	90	1	10/60	15
Pregnant women	Interview guide (Att 5d)	80	1	2	160
				Total	**220**

12B. **Estimated Annualized Burden Costs**

The annualized costs to the respondents are described in **Exhibit 12.3**. The United States Bureau of Labor Statistics' employment and wages estimates from May, 2016. (http://www.bls.gov/oes/current/oes_nat.htm) were used to estimate the hourly wage rate for the general public for the purpose of this GenIC request. The total estimated cost of the burden to respondents is approximately $8,971.73. This cost represents the total burden hours of obstetricians and gynecologists multiplied by the average hourly wage rate ($112.65) and the total burden hours of pregnant women multiplied by the average hourly wage rate ($23.86).

Exhibit 12.2: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Prenatal care providers	Eligibility Screener (Att. 5a)	5	$112.65	$563.25
Prenatal care providers	Interview Guide (Att. 5b)	40	$112.65	$4,506.00
Pregnant women	Eligibility Screener (Att 6a)	15	$23.86	$357.90
Pregnant women	Interview guide (Att 6b)	160	$23.86	$3,817.60
			Total $ 9,244.75	

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

There are no other costs to respondents for participating in this survey.

14. Annualized Cost to the Federal Government

The total annualized cost to the government is to carry out the data collection activities is $9,244.75. Funding to the awardees is being provided through the Funding Opportunity Announcement # CDC-RFA-OT13-1302 to the March of Dimes Foundation.

Exhibit 14.3: Annualized Cost to the Government

Expense Type	**Expense Explanation**	**Annual Costs (dollars)**
Direct Costs to the Federal Government	CDC Co-Project Lead (GS-14 0.20 FTE)	$23,362
	CDC Co-Project Lead (GS-13, 0.20 FTE)	$19,770
	Subtotal, Direct Costs	**$43,132**
CoAg Costs	**Annual Cooperative Agreement (**MOD # CDC-RFA-OT13-1302**)**	$150,000
	TOTAL COST TO THE GOVERNMENT	**$193,132**

15. Explanation for Program Changes or Adjustments

This is a new information collection request (ICR).

16. Plans for Tabulation and Publication and Project Time Schedule

Tabulation will include descriptive characteristics of respondents collected in the first part of the interview (e.g., city, age, education, employment status). Data collection will occur between April to May 2018, analyses will be carried out in June – July 2018, and the final data set and report will be submitted in August 2018. The project timeline is detailed in **exhibit 16.1**.

Exhibit 16.4: Project Time Schedule

Activity	**Time Schedule**
Develop data collection tools, sampling and data plans, study protocol, IRB and PD approvals	October 2017- Jan 2018
OMB Submission	Feb 2018
Recruitment	After OMB Approval
Data Collection	1-3 months after OMB Approval
Data analysis finalized and report drafted	4-6 months after OMB Approval

Final data set and final report submitted to CDC	7 months after OMB Approval

In compliance with the CDC policy on data management and access, we will develop a final, de-identified (names, other PII, and locations will be removed) qualitative database for this study along with the corresponding data documentation. This database will be made publicly available within 30 months of the end of data collection, if the final de-identified data are of sufficient quality and usefulness, and can be shown to result in generalizable value to science.

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

We do not seek approval to eliminate the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certification.

References:

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