GenIC Clearance for CDC/ATSDR

Formative Research and Tool Development

Supporting Statement A

Messaging to Improve Patient-Provider Communication and Engagement on Risks of Alcohol Use During Pregnancy

OMB number 0920-1154

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March 21, 2018

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A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests a 1-year Office of Management and Budget (OMB) approval for a new GenIC entitled "Messaging to Improve Patient-Provider Communication and Engagement on Risks of Alcohol Use During Pregnancy." The purpose of this study is to conduct formative research to assess perceptions among women of reproductive age regarding alcohol use during pregnancy, determine women's comfort with discussing alcohol use, contraception, and pregnancy with their health care providers, and examine provider comfort with and use of alcohol screening and brief intervention (SBI).

Fetal alcohol spectrum disorders (FASDs) are conditions that can result from prenatal alcohol exposure. Estimates of FASDs—a continuum of completely preventable disorders—are between 2 and 5 percent of school-aged children in the United States. The effects of FASDs include lower IQ, neurological damage, and a variety of behavioral disorders, which can significantly limit children throughout their lives and cause unnecessary burden on medical, educational, and social service systems. Excessive alcohol consumption also leads to a variety of negative health and social consequences that effect individuals, families, and communities.

Fortunately, effective prevention strategies are available to reduce alcohol consumption among women of reproductive age. However, it is difficult to craft public health messages and communication strategies to change alcohol-related attitudes and behaviors because of the range of knowledge and beliefs about alcohol use and pregnancy. Even though public health experts recommend alcohol SBI for adults in primary care settings, data indicate that only about one in six U.S. adults (17%) report ever discussing alcohol use with a health professional. A roughly equal share of pregnant women (17%), a population at greater potential risk of adverse health effects from alcohol, report ever having conversations about their consumption with health care providers. To develop an effective, consistent messaging strategy, a deeper understanding of how both women and healthcare providers think about and discuss alcohol use is needed. The research conducted under this GenIC will be used to inform the development of patient and provider materials and messages about how to discuss the risks of alcohol use during pregnancy.

As part of this work, CDC has contracted AIR and EurekaFacts to conduct an online survey with 500 healthcare providers (HCPs) along with 36 individual in-depth HCP interviews recruited from the larger sample of online survey participants. The online survey will allow for the examination of patterns and relationships as they relate to reported behaviors, attitudes, and experiences of healthcare providers who care for women of reproductive age. The topics for the survey were selected based on a thorough literature review which identified gaps in knowledge about alcohol SBI and FASDs. Together, the online survey and in-depth interviews will provide rich information on provider beliefs, attitudes, and cultural frames informing alcohol use; provider views on delivering services to women of reproductive age, and provider perceptions of self-efficacy and comfort delivering alcohol SBI and counseling patients. These data will support the development of appropriate messaging to help motivate providers to include alcohol SBI in their practice, build self-efficacy in delivering alcohol SBI, and allow for the development of tailored communication materials for healthcare providers based on their current motivations and practices in delivering alcohol SBI. Similarly, AIR and EurekaFacts will conduct 72 individual in-depth interviews in person with women of reproductive age (21 – 45 years of age). The interviews will investigate the knowledge, attitudes, and behaviors of women regarding pregnancy, contraception, and alcohol use, which will support the development of appropriate consumer-based messaging to improve patient–provider communication and engagement on risks of alcohol use during pregnancy.

A.2. Purpose and Use of Information Collection

The purpose of this study is to conduct formative research to assess perceptions among women of reproductive age regarding alcohol use during pregnancy, determine women's comfort with discussing alcohol use, contraception, and pregnancy with their healthcare providers, and examine provider comfort with and use of alcohol SBI. The research results will be used to inform materials and messaging for patients and providers about alcohol use during pregnancy.

The contractor will conduct all data collection related to the proposed study. There are three components to this study: 1) Online survey of healthcare providers; 2) Individual in-depth, telephone interviews with healthcare providers; and 3) Individual in-depth, in-person interviews with women of reproductive age. Data collection will consist of a screening process to facilitate recruitment of participants into the study. For the purposes of conducting the online survey and

individual in-depth interviews with healthcare providers, EurekaFacts will use the Healthcare Professional Panel from Dynata, a renowned commercial panel provider. The healthcare providers will be physicians or nurse practitioners in primary care. For the individual in-depth interviews with healthcare providers, participants will consist of a targeted mix of providers who currently deliver alcohol SBI, those who previously delivered alcohol SBI, and those who have never delivered alcohol SBI. For the individual in-depth interviews with women of reproductive age (21 to 45 years of age), the contractor will recruit through: 1) the EurekaFacts database of previous research participants in the desired geographical regions, 2) a general advertisement method, and 3) individual/direct recruitment with multiple modes such as individual emails and telephone recruiting. The EurekaFacts participant database includes approximately 30,000 individuals nationwide and is constantly refreshed and updated through our independent participant outreach methods in both English and Spanish. To ensure the quality of the data, EurekaFacts' policy states that respondents may only participate in qualitative research once every three to six months.

A.3. Use of Improved Information Technology and Burden Reduction

This study will consist of data collection using a one-time online survey for healthcare providers, a one-time individual in-depth telephone interview for healthcare providers who have already completed the online survey, and a one-time, individual, in-depth interview for women of reproductive age. To minimize respondent burden, an online survey will be used to collect information from the healthcare providers and individual in-depth interviews with healthcare providers will be conducted by phone.

In addition, minimal information will be collected by phone from potential participants who are women of reproductive age to ensure they are eligible for the study. The screening questions with potential participants who are women of reproductive age will be administered using a computer-assisted telephone interview (CATI) system, in a secure location to which only authorized personnel have access, or using an online survey to determine eligibility. Following the determination of eligibility, participants will be contacted by email to schedule an interview. The initial screening is short, estimated at 3 minutes. Eligible respondents will participate with informed consent and all responses will be kept private to the extent permitted by law. The briefness of the screening will reduce the burden to non-participants. Where possible and upon

consent from the participant, the contractor will audio-record the individual in-depth interviews, both telephone and in-person, to capture all information and help prepare reports.

A.4. Efforts to Identify Duplication and Use of Similar Information

To identify duplication and use of similar information, the contractor conducted an environmental scan of existing materials for healthcare providers, a literature review of research on alcohol SBI targeting women of reproductive age, and a literature review of research on the use of alcohol SBI among healthcare providers. In addition to reviewing published information, the contractor also searched for "gray" literature online. Duplication of this effort or the existence of similar information was not identified during this process.

From the environmental scan, several recent studies were identified that evaluate provider knowledge, attitudes, and behaviors (KABs) on alcohol use among patients, and specifically among pregnant women, but these focus on attitudes about the quantity of alcohol considered safe for pregnant women to consume. One key finding from these investigations noted that, "More research is needed to determine how often [providers] screen women of reproductive age for alcohol consumption and counsel pregnant women or women planning a pregnancy to avoid alcohol," a research question that this study explores (Anderson et al., 2010; Arnold et al., 2013; RTI, 2017; Zoorob, Aliyu, & Hayes, 2010).

A.5. Impact on Small Businesses or Other Small Entities

The information will not be collected from small businesses or other small entities.

A.6. Consequences of Collecting the Information Less Frequently

This is an ad hoc data collection (i.e., a one-time study to develop a messaging strategy that does not require periodic collection of data). There are no legal obstacles to reduce burden. The present study will provide the primary data needed to address the goals of this study. If this formative research was not conducted, information needed to inform the development of messaging and materials for women of reproductive age and healthcare providers about how to discuss the risks of alcohol use during pregnancy would not be gathered.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

The Federal Register notice was published for this collection on July 18, 2016, Vol. 81, No. 137, pp. 46680. No other public contacts and opportunities for public comments were received.

CDC project staff collaborated with the contractor on the study design, screening instruments, and data collection instruments. Contract staff are trained and experienced in conducting formative research on sensitive topics. CDC also recognizes the importance of gaining valuable insights from experts who have content expertise and experience working with various consumer and provider audiences. Individuals consulted with and their roles are listed in **Exhibit A.8.1**. No major problems were identified that could not be resolved.

Exhibit A.8.1. CDC Project Staff and Other Consultants

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A.9. Explanation of Any Payment or Gift to Respondents

The healthcare provider online survey is expected to take 15 minutes to complete. The individual in-depth interviews for healthcare providers will take approximately 30 minutes to complete, while the individual in-depth interviews for women of reproductive age will each take about 60 minutes to complete. Dynata will distribute survey and in-depth interview incentives to the healthcare provider participants who complete the survey and who complete the in-depth interview. Dynata, a commercial online panel provider, will manage the healthcare provider online survey and identify participants for the in-depths provider interviews. Using an online provider panel is an efficient and cost-effective way to get access to healthcare providers. The costs of recruiting and interviewing providers based on a list sample would be beyond the resources available for this effort. Dynata uses a point system for their panel participants which then translates into dollars once the participants redeem the points. The cash equivalent that healthcare providers will receive for participating in this data collection effort are: $10 for completion of the online survey and $100 for the individual in-depth interviews. The incentive amounts commonly offered to healthcare provider are between $125-175 for a 30-minute interview. Incentives are used, in a non-coercive manner for multiple federal data collection efforts, including the National Health and Nutrition Examination Survey and the National Survey of Family Growth (Bureau of Labor Statistics, 2015). Healthcare providers are typically offered more in order to gain cooperation and ensure a robust sample from this population which is

harder to reach than the general public. Provision of incentives to healthcare providers will also help maximize the response rate for this data collection request.

Women of reproductive age who participate in individual in-depth interviews will receive a $40 gift card as a token of appreciation at the end of the interview. The incentive amounts commonly offered to participants from the general public fall between $20 and $50. Numerous empirical studies have shown that incentives can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999). These token of appreciation amounts were determined through discussions with contract staff with expertise in conducting interviews with the study population and interviews about alcohol. Removing the incentive could negatively affect recruitment, which could threaten the development of a messaging strategy resulting from this testing.

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

There are three components to the data collection:

1) Online survey of healthcare providers: types of information collected includes general demographic data (e.g., geographic location, age range, gender, clinical practice behaviors and experiences (e.g., how alcohol screening is done, if counseling is provided), and attitudes related to alcohol use and pregnancy (e.g., what information is provided to women of reproductive age). The online survey is administered by an independent third-party healthcare panel provider. Participants have a pre-existing user account with the healthcare panel provider. CDC is not privy to the personally identifiable information (PII) data collected or maintained by the panel provider, including user credentials.

2) Individual in-depth, telephone interviews with healthcare providers: types of information collected includes provider contact information (for scheduling purposes only), provider knowledge, attitudes, and beliefs about alcohol screening and brief intervention, how confident they feel about discussing alcohol use with women, and their personal experiences discussing this topic with their female patients.

3) Individual in-depth, in-person interviews with women of reproductive age: types of information collected includes personal contact information (for scheduling purposes only), data

on women's behaviors and attitudes related to alcohol, birth control, and pregnancy, and insights regarding interactions with healthcare providers about alcohol use, birth control, and pregnancy.

Screening, consent, data collection instruments, and recruitment materials for the study are provided in **Attachments A** through **K**. All instruments include the Paperwork Reduction Act (PRA) disclaimer and burden information along with the currently valid OMB control number. Consent forms include additional information indicating that participation is voluntary, research purpose, and how research findings will be used. For in-person interviews, this information will be read to each respondent before the interview begins. For the healthcare provider online survey, the consent form will be provided online, and participants will give consent prior to entering the survey. All consent forms are included in **Attachments A-C**. For healthcare provider individual in-depth interviews, providers will give oral consent by telephone prior to beginning the telephone interview. Women who participate in the individual in-depth interviews will have a consent form sent to them for completion prior to appearing in-person for the interview. If they have not completed the consent form prior to the interview, they will be given a consent form to complete before the interview. During the introduction to the interview, the interviewer will review key parts of the informed consent, which will include informing participants of the following:

1. The interview is voluntary; participants may choose not to answer any question and can end participation at any time.
2. The contractor will report findings in summary form so that participants cannot be identified and that their identifiable information will be kept secure and separate from the interview notes and audio recordings.

If there is a major change to the data management process, the contractor will attempt to contact all participants via email and/or phone. Participants will be provided a new consent form which highlights the original intent of the study as well as the new intent, which can be mailed back to the researchers. If participants cannot be reached, they will be removed from the database and all future analyses. All individuals recruited for the study will receive information on how to reach the contractor if they have concerns about their PII. Healthcare provider participants, recruited through a third-party healthcare panel provider, can also raise concerns

directly with the panel provider. Healthcare providers and women of reproductive age who agree to participate in the in-depth interviews are provided the contractor's contact information during the consent process. Concerns can be made at any time before, during, or after the interviews and participants can express these concerns in person, by phone, or email.

Should a participant raise concerns on the accuracy of their data, such as the need to update contact information, these changes will be applied directly to the data file and confirmed with the participant over the phone or via email.

The contractor will conduct the formative research for this study in the following ways:

Healthcare provider online survey and individual in-depth interviews: The contractor will use an independent third-party healthcare panel provider to recruit healthcare providers to participate in an online survey. As the healthcare providers are being contacted through an existing panel, it is anticipated that most providers who are contacted will be eligible and willing to participate. Healthcare providers who participate in the survey will be asked questions about their specific occupation (e.g., physician, nurse), medical specialty, and geographic location (urban vs. rural). Approximately 600 healthcare providers will be contacted to reach 500 completed surveys. Screening questions are included at the beginning of the healthcare provider online survey instrument in **Attachment D,** and the corresponding screenshots are found in **Attachment E**.

The final questions of the online survey instrument ask participants if they are interested in participating in a 30 minute in-depth interview. If they consent, they are asked to provide their name, phone number, and email address. The purpose of collecting this PII is to enable the contractor to contact these participants to schedule and conduct the in-depth interviews with a sample of healthcare providers. Seventy-two providers will be contacted to via email or by phone to identify 36 eligible participants. The sampling plan for both types of data collection from healthcare providers are in Supporting Statement B. The interview guides for provider in-depth interviews are included as **Attachment F**. Interviewing a sample of healthcare providers via in-depth interviews will allow the contractor to obtain greater detail on specific experiences of providers on how they talk to their female patients about alcohol use during pregnancy and their

practices of alcohol screening and brief intervention. This information will provide additional insights to complement the quantitative findings from the online survey.

In-depth interviews with women of reproductive age: The contractor anticipates screening up to 300 women to obtain 72 respondents. EurekaFacts will utilize a multi-pronged recruitment approach which will include three main methods: 1) recruitment using the EurekaFacts database of research participants in the desired geographical regions, 2) a general advertisement method, and 3) individual/direct recruitment with multiple modes such as individual emails and telephone recruiting. Specific methods and resources (**Attachment G**) will be used to recruit participants, as follows:

1. EurekaFacts participant recruitment: Contact female members of our database of individuals and households in the desired geographic location, offering a brief online screener to promote interest and participation.

2. General advertisements method: Use of classified advertisements or more general announcements to appear in online and print versions of local newspapers and news websites.

3. Direct recruitment via multiple contact methods: Email and phone recruitment efforts utilizing emails and phone contact lists available from a highly reputable commercial vendor that provides similar direct marketing outreach services for major national corporations and consumer brands. Referrals from personal networks at the time of responding to general appeals and after completing interviews will also be pursued.

Questions asked to identify women who are eligible to participate in in-person, in-depth interviews include questions on age (range of age group options), race/ethnicity, education (e.g., high school, college or less, college graduate), alcohol use in the past 3 years (yes/no), pregnancy status, and income (range of income options). The purpose of these questions is to determine eligibility for participation in the interviews and to ensure adequate representation of participants with different backgrounds and experiences. Study recruiters will then collect the names, emails, mailing addresses, and phone numbers of those women who are eligible and who agree to participate in the in-person, in-depth interviews. The sampling plan for this work is included in

Supporting Statement B. Screening data for the individual in-depth interviews with women of reproductive age will be collected using a standardized screening instrument (**Attachment H**), with screenshots of the screener and the landing page found as **Attachments I** and **J,** respectively). The corresponding interview guides for each audience segment are included as **Attachment K**. Data collection for women of reproductive age participating in the individual in-depth interviews will include participants from New York, NY; Atlanta, GA; Chicago, IL; and San Diego, CA.

In determining processes for managing PII, the contractor uses the Least Privileged model. Only individuals directly involved in the data collection will have access to PII. The project director will assess each team member to determine access to PII. The staff who will have access to PII are the telephone schedulers and their supervisors, the statistician, and the interviewers.

It is not anticipated that telephone eligibility screening will be utilized, but should telephone support be needed, these telephone research recruiters only have access to a web link where they input PII as part of the screening process. After recruitment has concluded, administrative and technical controls will be used to discontinue access to PII. All in-depth interview participants (healthcare providers and women) will be assigned a unique identifier that is linked to data collected during the interviews, thus protecting their PII during data cleaning and analysis. The statistician who assigns unique identifiers to participants will maintain access to PII on a password-protected computer for one year before these data are destroyed.

The interviewers will also require access to PII in order to conduct the telephone or in-person interviews and confirm contact information with participants. All individual in-depth interviews will be audio-recorded for the purpose of completing the final reports. All audio recordings will be destroyed after notes have been verified and no links will be maintained to any data collected. CDC will only receive de-identified data from the contractor for this one-time data collection. No PII will be shared with CDC or other agencies or organizations. PII will be stored temporarily. Protection and storage requirements of PII is outlined in the Security Assessment and Authorization package, including a separate Privacy Impact Assessment developed by the US. Department of Treasury.

Staff are trained on PII management on a continual basis: upon hire and annually after that. Every project has an internal kickoff meeting where the PII guidelines are reviewed and are tailored for the specific project. PII security practices including the following:

Administrative Controls:

1. All contractor staff sign a confidentiality and non-disclose clause as part of their employment agreement that provides policy and contractual protection against unauthorized access, use or dissemination of any data made available to them as a result of their employment.

2. Any PII data elements are identified at the onset of the project and protocols and procedures are developed in order to ensure the data is restricted for access.

3. All staff receive training on the confidentiality procedures and requirements applicable to the project including use and protection of PII.

Technical Controls:

1. Contractor servers are protected through logic and physical firewalls and all passwords are required to be complex. PII stored electronically is kept by the contractor only during the time required for performance of the contract and the information is compartmentalized and encrypted or password protected to provide greater security.

2. Data is protected in accordance with the Federal Information Security Management Act (FISMA).

3. The contractor owns and operates equipment that wipes data from storage media devices that adheres to a 3 Pass DoD 5220 22-M Standard to ensure there is no readable data left. The media is then turned over to an approved third party for certified physical destruction and documentation of serial numbers.

Physical Controls:

1. The data collection system is protected in a secure environment with controlled access.

2. PII collected in physical form (paper surveys) is maintained under lock and accessible to authorized personnel only.

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

This project has received IRB approval through AIR's IRB. IRB approval was granted on 04/10/2018 and will not expire, as the research was determined to be exempt. The current IRB approval letter is included as **Attachment L**.

In the course of conducting this research, all respondents will be assured that the information will be used only for the purpose of this research and will be kept secure to the extent allowable by law, as detailed in the informed consent forms (see **Attachments A-C**). Respondents will be assured that their answers to the study screener and data shared during the individual in-depth interviews and online survey will not be shared with anyone outside the research team and that their names will not be reported with responses provided. Respondents will be informed that the information obtained will be combined into a summary report so that details of individual responses cannot be linked to a specific participant.

The contractor maintains restricted access to all data preparation areas (i.e., receipt and coding). All data files on multi-user systems will be under the control of a database manager, with access limited to project staff on a "need-to-know" basis only.

The individual in-depth interviews with women of reproductive age ask questions of a sensitive nature, including questions related to alcohol use and pregnancy. This measurement of sensitive alcohol-related questions is necessary to create a messaging strategy aimed at improving alcohol SBI delivery for women at risk of an alcohol-exposed pregnancy. The study screener, **Attachment H**, will ask women if they have used alcohol at any time in the prior three years. The screener includes some questions regarding pregnancy status and whether the participant is sexually active, which some of the participants may potentially consider sensitive. These questions are necessary to ask to achieve the study goals. The participant may refuse to answer any of these questions. Study screening questions will also address race/ethnicity, gender, level of education, and age. The screeners for the data collection with healthcare providers will include only questions about the providers' occupation, specialty, and urbanicity of their location and do not include any sensitive questions.

A.12. Estimates of Annualized Burden Hours and Costs

The total annualized response burden is estimated to be **270 hours**. Exhibit A.12.1 provides details about how this estimate was calculated. The healthcare providers will be recruited through Dynata where consent to participate in the online survey will be obtained. EurekaFacts anticipates screening 600 healthcare providers to obtain 500 respondents for the healthcare provider online survey. Screening and completion of the online survey is estimated to

take 15 minutes (150 burden hours). From those survey participants who volunteer for the healthcare provider in-depth interview, EurekaFacts will reach out to 72 healthcare providers to identify 36 participants eligible to participate in the in-depth interview. The consent process is estimated to take approximately 8 minutes (5 burden hours). In-depth interviews with healthcare providers are estimated to take 30 minutes (18 burden hours). EurekaFacts also anticipates screening 300 women (15 screening burden hours) resulting in 72 women completing individual in-depth interviews (10 consent burden hours; 72 interview burden hours).

Exhibit A.12.1 Annualized Burden Hours

Type of Respondent	**Form Name**	**Number of Respondents**	**Number of Responses per Respondent**	**Average Burden Per Response (in hours)**	**Total hours**
Online Survey – Consent for Healthcare Providers	Attachment A	500	1	3/60	25
Online Survey – Healthcare Providers *(includes Survey Screener & Screener Questions for In-depth Interviews)*	Attachments D, E+	500[a]	1	15/60	125
In-Depth Interviews – Consent for Healthcare Providers	Attachment B	36*	1	8/60	5
In-Depth Interviews – Healthcare Providers	Attachment F	36[a]	1	30/60	18
In-depth Interviews with Women – Screener	Attachments H, I+, J+	300	1	3/60	15
In-depth Interviews with Women – Consent	Attachments C	72	1	8/60	10
In-depth Interviews – Women	Attachment K	72[a]	1	60/60	72
Total					**270**

+ Corresponding screen shots for information
* Subset of initial contact group, not double counted in the total number of respondents
[a] Estimated number of actual participants will be somewhat less than confirmation numbers

Because the wage rate category for women of reproductive age (or even whether they will be employed at all) is unknown, $24.34 per hour was selected as this is an estimate of mean hourly wage for all occupations across the country (Bureau of Labor Statistics, 2018). The wage rate of $101.63 per hour was also drawn from the Bureau of Labor Statistics (2018) and used as

an estimate of mean hourly wage for all healthcare providers. Exhibit A.12.2 details the total annualized cost to all study respondents which is **$19,942.**

Exhibit A.12.2 Annualized Cost to Respondents

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Online Survey – Consent for Healthcare Providers	Attachment A	25	$101.63	$2,541
Online Survey – Healthcare Providers *(includes Survey Screener & Screener Questions for In-depth Interviews)*	Attachments D, E+	125	$101.63	$12,704
In-Depth Interviews – Consent for Healthcare Providers	Attachment B	5	$101.63	$508
In-Depth Interviews – Healthcare Providers	Attachment F	18	$101.63	$1,829
In-depth Interviews with Women – Screener	Attachments H, I+, J+	15	$24.34	$365
In-depth Interviews with Women – Consent	Attachments C	10	$24.34	$243
In-depth Interviews – Women	Attachment K	72	$24.34	$1,752
Total				**$19,942**

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

There are no other costs to respondents or record keepers.

A.14. Annualized Costs to the Government

The average annualized cost to the Federal Government to collect this information is $246,196. The federal government personnel estimate is based on cost of the two CDC staff: CDC Behavioral Scientist (GS-14) and CDC Behavioral Scientist//Technical Monitor (GS-13). Federal staff responsibilities include overall management and oversight of the project and provision of content matter expertise in the development of the research strategy and data

collection instruments. Contractor costs include direct labor for development of instruments, data collection, analysis and reporting for both phases of the formative research. Other direct contractor costs include subcontractors, travel, and facility rental, participant recruitment and incentives; and indirect costs such as fringe, overhead, general and administrative fees (**Exhibit A.14.1**)

Exhibit A.14.1. Government Costs

		Percent Time	**Total ($)**
Federal Government Personnel Costs	CDC Behavioral Scientist (GS-14)	10%	$13,716
	CDC Behavioral Scientist (GS-13), Technical Monitor	10%	$11,912
Total Contractor Costs	Subcontractor, travel, facility rental, participant recruitment, incentives, personnel, fringe, overhead, general and administrative fees	n/a	$220,568
Total Annualized Cost to Government			$246,196

A.15. Explanation for Program Changes or Adjustments

No change in burden is requested as this is a new information collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Data from the healthcare provider online survey will be used to perform quantitative research analysis. The in-depth interviews of the healthcare providers and the women of reproductive age will be used for qualitative research analysis. Healthcare providers will be segmented based on alcohol SBI usage into three groups: 1) currently use alcohol SBI, 2) used alcohol SBI previously, but no longer do so, and 3) never used alcohol SBI. Women of reproductive age, who are also sexually active and have consumed alcohol in the past three years, will be segmented based on pregnancy status and intention into three groups: 1) Women who are not currently pregnant and have no intention to become pregnant in the next 12 months, 2) women who are not currently pregnant and do intend to become pregnant in the next 12 months, 3) women who have given birth in the past 12 months. All the data obtained will be entered into an electronic data matrix by the contractor during the data collection process and

stored on a password-protected computer. The contractor will conduct thematic or grounded theory analysis of the data to understand participants' reactions to the interview questions in a rigorous and detailed manner. We will use NVivo (qualitative software) to aid with the analysis. Contractor analysts will analyze the data and produce a written report describing the major findings from the in-depth interviews and survey.

Key events and reports to be prepared are listed in **Exhibit A.16.1**.

Exhibit A.16.1. Project Activities and Time Schedule

Activity	Time Schedule
Release online survey to healthcare provider participants	1 week after OMB approval
Complete online survey	1 month after OMB approval
Begin recruitment for healthcare provider in-depth interviews	1 week after survey completion
Begin recruitment for in-depth interviews with women of reproductive age	2 weeks after OMB approval
Complete individual in-depth interviews with healthcare providers and women of reproductive age	3 months after OMB approval
Draft report due	5 months after OMB approval
Final report due	6 months after OMB approval

The main reporting mechanism will be in the form of a final formative research report submitted to CDC. The final report will include the following information: an executive summary, overview of background literature to provide contextual information about the purpose of the research, a detailed summary of the formative research methods and results, a discussion of findings, strengths and limitations of the research, and future directions regarding message strategy.

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

Approval to eliminate the expiration date is not needed.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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