Safer Use of Medications During Pregnancy

NCBDDD Generic Information Collection Request
OMB No. 0920-0990

Supporting Statement – Section A

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81. **Section A – Justification**
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1. Circumstances Making the Collection of Information Necessary

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84. **Background**
85. This data collection is being conducted using the Generic Information Collection mechanism of the National Center on Birth Defects and Developmental Disabilities (NCBDDD) – OMB No. 0920-0990. The respondent universe for this data collection aligns with that of the NCBDDD. Data will be collected from women of childbearing age (18–44) to assess their knowledge, awareness, behaviors, and access to information about medication use during pregnancy.
86.
87. This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241).
88.

89. Medication use among pregnant women and its impact on the health of the mother and fetus is a growing public health concern. Although little information is available about the safety of many medications during pregnancy, it is widely accepted that certain medications, such as isotretinoin, can cause serious birth defects if taken during pregnancy (Fisher, 2008). Other medications, when taken during pregnancy, have also been associated with birth defects and adverse pregnancy outcomes (Briggs, Freeman, & Yaffe, 2008).

90. The first trimester is an especially critical time for the development of a fetus, so medication use during this period is of particular concern. In the past three decades, the use of prescription medication during the first trimester of pregnancy has increased by more than 60%, with estimates of prescription medication use during the first trimester of pregnancy ranging from 29% to 48% (Bercaw, Maheshwari, & Sangi-Haghpeykar, 2010; Mitchell et al., 2011). The use of any medication, prescription or over-the-counter (OTC), is estimated at roughly 94% (Mitchell et al., 2011). The use of medication has increased, as has the overall number of medications used by pregnant women (Mitchell et al., 2011). The average number of medications, both prescription and OTC, has increased 68% in the past three decades, from 2.5 in 1976–1978 to 4.2 in 2006–2008. Furthermore, the percentage of pregnant women using four or more medications has tripled during this time (Mitchell et al., 2011).

91. Decisions on whether or not to use prescription and/or OTC medication during pregnancy fall largely on women and their health care providers. Despite the widespread use of medications during pregnancy, few researchers have examined the knowledge and attitudes toward medication use and exposures during pregnancy among women in the United States. Studies from Europe and the Middle East indicate that although women are often unaware of the safety of specific medications (Damase-Michel, Christaud, Berrebi, Lacroix, & Montastruc, 2009), they nonetheless have general safety concerns about taking medications during pregnancy (Mashayekhi, Dilmaghanizadeh, Fardiazar, Bamdad-Moghadam, & Ghandforoush-Sattari, 2009; Nordeng, Koren, & Einarson, 2010a). The source of information for women regarding medication use during pregnancy is unclear, although (Santucci, Gold, Akers, Borrero, & Schwarz, 2010) reported that many women of childbearing age believe that health care providers should initiate the conversation and provide information on the risks associated with medication use. Nonetheless, it is not clear that providers are always communicating that information. As Pashley and O'Donoghue (2009) reported, the majority of women in their study did not feel that their general practitioner provided adequate advice on medication use during pregnancy.

92. Information is limited on whether and how much health care providers share information about medication use. However, one study found that 90% of obstetrician-gynecologists reported that all or many of their pregnant patients asked about the effects of prescription medication on the fetus (Morgan, Cragan, Goldenberg, Rasmussen, & Schulkin, 2010a){Morgan, 2010a #12}. Similarly, 98% of physicians always asked about prescription medication use, and 86% always asked about OTC medication use during a patient's initial prenatal appointment (Morgan, Cragan, Goldenberg, Rasmussen, & Schulkin, 2010b). At the same time, Eisenberg, Stika, Desai, Baker, and Yost (2010) reported that 61% of primary care providers felt that medical school inadequately prepared them to deal with teratogenic medications, and 41% of obstetrician-gynecologists reported that they prescribed a medication without having sufficient information about its effects on the fetus (Morgan et al., 2010b). Barriers to counseling women about teratogenic risks include concerns about liability, difficulty finding information on drug safety during pregnancy, and the risk that patients may not use necessary medications due to anxiety about teratogenic risks (Eisenberg et al., 2010; Morgan et al., 2010b).

93. The purpose of this study is to conduct formative research with women of childbearing age (18–44) to assess their knowledge, awareness, beliefs, and access to information about medication use during pregnancy. Specifically, our research will focus on learning how women with chronic or acute conditions make decisions about medication use during pregnancy, including what sources of information they identify as credible.

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99. **Privacy Impact Assessment**
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101. Overview of the Data Collection System

102. We propose conducting a study with two components, consisting of virtual focus groups and follow-up interviews. Virtual focus groups have many benefits, including cost effectiveness, anonymity, and ability to reach a sample across national markets. However, there is the potential for a loss of in-depth data obtained through virtual focus groups as opposed to in-person focus groups. To account for the potential loss of depth, we plan to conduct follow-up telephone interviews with 1-2 participants in each focus group to probe deeper on issues that emerge during the focus groups.

103. In the first component, six virtual focus groups (VFGs) and follow-up telephone interviews with up to 12 participants will be conducted with women of childbearing age (18-44) via the Internet rather than in person. The virtual focus groups are targeted to one of six audience segments. Table 1 presents the proposed audience segmentation scheme.

104. Table 1: Focus Group Segmentation (n = 6 focus groups)

105. **Respondents**	106. **Medication Status**	107. **Number of Focus Groups**
108. Women age 18-44 planning to become pregnant in next 1–2 years who . . .	109. Currently take prescription pain medication for chronic pain	110. 1
	112. Currently take a prescription antidepressant	113. 1
	115. Currently use a prescription asthma medication	116. 1
117. Women age 18-44 who had a baby	118. Took a short term	119. 1

within the last year who . .	medication for a condition that arose during previous pregnancy	
	121. Took a prescription antidepressant during pregnancy	122. 1
	124. Used a prescription asthma medication during pregnancy	125. 1
126. **TOTAL**	127.	128. **6 groups**

129.

130. RTI International developed a screener questionnaire that will be used to identify eligible participants for this study based on the segmentation strategy (see **Attachment 1**). We will partner with a professional recruitment firm, Manthan Panels, to recruit the specific sample of women. The recruiter will use the questionnaire to screen and assign participants to groups. To ensure that we have a sample that meets our criteria and also includes a mix of age, race, and income, Manthan will send targeted recruitment emails (see **Attachment 16**) to individuals in their recruitment database who represent a mix of these variables. The screening process will then serve to verify demographic variables such as these and identify participants who meet the remaining screening criteria. As a result of the targeted, pre-screening, the screener calling can assign participants to groups during the screening process. The recruiter will recruit a maximum of 24 participants per group, resulting in an actual group size of no more than 12 participants To conduct the virtual focus groups, we will partner with an online focus group vendor, Itracks, using a live chat platform. We will host the group as a real-time, live chat session, which allows the moderator to post questions and probes and allows participants to type responses visible to the moderator and all other participants. At the beginning of each focus group, participants will be asked to complete a consent form (see **Attachments 2, 2a**). These groups will last approximately 60–90 minutes and involve up to 12 participants in each group. A trained RTI moderator will lead the group and use a semi-structured moderator guide (see **Attachments 3, 3a, 5, 5a, 7, 7a, 9, 9a, 11, 11a, and 13, 13a**) to ask questions, probe for details, and lead participants in an open discussion. The virtual focus groups will be semi-structured, and the types of discussion questions will focus on current medication use, how medication use changes

during pregnancy, risk perceptions related to medication use during pregnancy, experiences with health care providers, and trusted sources and organizations for information about medication use during pregnancy.

131. During the virtual groups with consumers, the RTI team will observe participants and select those who offer compelling or noteworthy experiences and responses for follow-up interviews (see **Attachments 4, 6, 8, 10, 12, and 14**). Participants will be selected based on these criteria:

- Actively engaged in virtual focus group;
- Shared experiences related to struggling with a decision to continue/start medication during pregnancy;
- Responded that they rely on more than one source of information for medication use during preconception/pregnancy;
- Provided a detailed response to the message testing questions.

132.

133. The RTI team will ask participants from each consumer group if they wish to participate in a follow-up telephone interview to describe their responses in more detail and provide additional information about their experiences. RTI will select two participants from each group, for a total of 12 participants. The follow-up interviews will take about 30 minutes and will be moderated by a trained RTI team member. Interviews will be audio-recorded and professionally transcribed. The follow-up interviews will be semi-structured, and designed to go more in-depth to specific experiences and narratives related to factors that affect decision-making about medication use during pregnancy.

134. Identification of Website(s) and Website Content Directed at Children Under 13

135. No website content will be directed at children under 13 years of age.

136.

137. **2. Purpose and Use of the Information Collection**

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139. Privacy Impact Assessment

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(i) Why the information is being collected

141. The National Center for Birth Defects and Developmental Disabilities (NCBDDD) at the CDC is requesting approval to conduct formative research with female consumers who are planning a pregnancy or who have recently given birth to learn more about their knowledge, attitudes, beliefs and behaviors regarding medication use during pregnancy. Findings from the formative research will be used to create a communication plan related to *Treating for Two campaign*. If we do not conduct this formative project,

CDC will not have the information it needs to create up-to-date and effective educational and communication materials, as part of the communication plan.

(ii) Intended use of the information

142. We will use the consumer focus groups to provide insight regarding the general questions listed below. Given, however, that we are recruiting small convenience samples, we will not actually be able to answer these questions on behalf of all women in this demographic or even subpopulations. Rather, this information is designed to help develop messages that would speak to the needs of at least some women in this demographic.

- How does having a chronic condition that requires ongoing medication maintenance (e.g., pain, depression, and asthma) influence women's knowledge, attitudes, and behaviors regarding medication use during preconception and pregnancy?
- Do consumers create a treatment plan prior to pregnancy? To what extent do women perceive monitoring medication use as important during pregnancy compared with other behaviors?
- How does having an acute condition during pregnancy influence women's knowledge, attitudes, and behaviors regarding medication use during preconception and pregnancy?
- For which symptoms do pregnant women most need to seek advice from a doctor?
- What messages do pregnant women and women of childbearing age receive from providers and other sources?
- What messages or information do pregnant women and women of childbearing age wish they have/had that they are not receiving?
- How do pregnant women and women of childbearing age weigh risks and benefits of medication use during pregnancy, considering both the baby's health and their own health? [Present a scenario or ask for experiences.]
- If risk of adverse fetal outcomes from medication use is unknown, how do women make decisions?
- In the absence of information, do women continue to take medications or discontinue use?
- Do women believe risk information applies to them (vs. others)?
- What types of risks are women most worried about (birth defects, miscarriage, preterm birth, global harm to self or baby?)
- How do women's medication use behaviors change when planning for a pregnancy or when pregnant?
- How do women become aware that a medication change is necessary? How is that information communicated to them?
- When do women perceive is the optimal time to change medication use in relation to becoming pregnant?
- When do women actually change medication use in relation to pregnancy?
- How do past experiences affect women's medication use in future pregnancies?
- What are the barriers and facilitators for pregnant women and women of childbearing age to adhere to medication use recommendations during preconception and pregnancy?
- How does health insurance play a role?

- Which source(s) or who influences women's knowledge, attitudes, and beliefs about medication exposure during preconception and pregnancy?
- Whose opinion matters most to women?
- How do women handle conflicting information?
- How do women interact around and share information?
- How many and what types of providers do pregnant women and women of childbearing age access and receive medication from?
- How do these providers interact around and share information?
- Who do women perceive is their primary point of contact for questions about medication use during pregnancy?
- How do women assess the credibility of information?
- How do women assess the credibility of sources?
- What are women's impressions of currently available resources?
- What is the preferred type of resource for women about medication safety during pregnancy? [Conduct possible poll on preferred products and channels with follow-up discussion.]
- What are the preferred channels? [How frequently do consumers need messages/reminders about safe use of medication before pregnancy? Probe on mobile technology, apps, TV, and text messaging.]
- What are the most credible sources of this information?
- What features make it credible?
- How could these resources be improved?

(iii) Impact on privacy to respondents

143.

144. The screening questionnaire (see **Attachment 1**)to determine eligibility, the consumer focus groups (see **Attachments 3, 3a, 5, 5a, 7, 7a, 9, 9a, 11, 11a, and 13, 13a**), and the follow-up interviews (see **Attachments 4, 6, 8, 10, 12, and 14**) will include some questions on sensitive information such as planning for pregnancy and reproductive health. However, data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. Identifying information through the screener will be collected by the professional recruiting firm, but only for recruiting purposes and will not be attached to findings.

145. Participation in the web focus groups and telephone interviews is voluntary. Respondents will be advised that all focus group data will be treated securely and will not be disclosed. Neither names nor contact information will be included in any data files, and analyses will be conducted using a de-identified data file. De-identified raw data will reside on a password protected share drive at RTI International. Responses will be aggregated and a summary report provided to the CDC and March of Dimes.

146.

3. Use of Improved Information Technology and Burden Reduction

147.

148. Research staff will conduct six virtual focus groups with consumers via the Internet rather than in person. To conduct the virtual focus groups, we will partner with Itracks, an online focus group vendor using a live chat platform. We will host the group as a real-time, live chat session, which allows the moderator to post questions and probes and allows participants to type responses visible to the moderator and all other participants. At the beginning of each focus group, participants will be asked to complete a consent form (see **Attachments 2, 2a**).These groups will last approximately 60–90 minutes and involve up to 12 participants in each group. A trained RTI moderator will lead the group and use a semi-structured moderator guide to ask questions, probe for details, and lead participants in an open discussion.

149. Conducting the virtual focus groups on the internet ensures convenient on demand access by the respondents. Virtual data collection will offer important benefits to this study, including

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- offering participants more privacy and anonymity (which may be important for women who may have chronic conditions or who may perceive taking medication during pregnancy as a sensitive topic);
- allowing us to recruit very specific populations from a national sample and allowing people to participate at a location of their choosing; and
- producing transcripts instantaneously, and because travel time for staff is eliminated data analysis can commence immediately, which will result in more rapid turnaround of topline reports.

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4. Efforts to Identify Duplication and Use of Similar Information

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153. There are no other studies that have been documented in the literature reporting on efforts to identify different perspectives on and experiences with medication use during pregnancy.

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5. Impact on Small Businesses or Other Small Entities

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156. There is no burden on small businesses or small entities. No small businesses will be involved in this activity. The virtual focus groups and follow-up interviews will be completed at the convenience of the participants and will not impact the participants' employers.

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6. Consequences of Collecting the Information Less Frequently

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159. This request is for a one time data collection. There are no legal obstacles to reduce the burden.

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

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162. There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

163.

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

164.

A. This data collection is being conducted using the Generic Information Collection mechanism of the NCBDDD – OMB No. 0920-0990. A 60-day Federal Register Notice was published in the Federal Register on March 6, 2013, Vol. 78, No. 44; pp. 14553-14554. One non-substantive comment was received in response to this notice.

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B. Project Partners and Collaborators.

167.

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189. 914-997-4501- Fax
190. jbiermann@marchofdimes.com

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9. Explanation of Any Payment or Gift to Respondents

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193. Upon full completion of the study, it is proposed that respondents will be given $50 for the 90 minute (1 1/2 hour) focus group, and $25 for the 30 minute follow up interviews for their interest, effort, and possible childcare costs. This amount is comparable to what has been the level of reimbursement for the target audiences in similar CDC funded activities. Women of childbearing age are often more difficult to recruit than more general audiences because they often have children and need to cover childcare costs to be able to participate in the focus group session. The incentive needs to be enough to help the participants cover outside childcare costs if needed. It is assumed that the incentive the women receive for participating in the groups would go toward the cost for off-site childcare to make it possible for them to participate. As shown by the literature referenced below, the payment of incentives can provide significant advantages to the government in terms of direct cost savings and improved data quality.

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195. There have been citations in the literature referencing the importance of monetary compensation for focus group participation. Krueger (1994) indicates that offering minimal levels of monetary compensation will help ensure that sufficient numbers of participants will attend thereby yielding useful results. Further, in a meta-analysis of 38 experiments and quasi-experiments, Church (1993) found that providing cash incentives for participation was far more effective than nonmonetary gifts in generating survey response, and prepaid monetary incentives yielded an average increase of 19.1 percentage points over comparison groups. Finally, findings related to the importance of monetary incentives are corroborated in the National Adult Literacy Survey by Berlin (1992) and colleagues (OMB No. 1850-0654, exp. 8/31/1993), and the National Survey of Family Growth.

196. We offer the following justification for our use of these incentives based on our 20-year history of similar research studies:

1. **Improved coverage of specialized respondents or rare groups**: The proposed data collection includes hard-to-reach women who have used medications during pregnancy, some of which may be considered stigmatized. To develop appropriate social marketing campaigns to address these groups' unique informational needs, it is imperative that sufficient numbers are included in the data collection. Yet, based on our prior experience, we anticipate that it will be challenging to identify and engage such participants in the formative research. Provision of an incentive is necessary to ensure that a sufficient number of respondents from hard-to-reach subgroups participate in the data collection.
2. **Reduced recruiting costs:** This incentive amount is cost-effective because the cost of a no-show is roughly 10 times the cost of paying the incentive. Further, lower participation rates will likely impact the project timeline because participant recruitment will take longer and, therefore, data collection will be slower.
3. **Data quality:** Because providing an incentive should increase response rates, it should also significantly improve validity and reliability to an extent beyond that possible

through other means. Recruiting with incentives arguably results in less bias. Previous research suggests that providing incentives may help reduce sampling bias by increasing rates among individuals who are typically less likely to participate in research (such as those with lower education, e.g., Guyll et al., 2003). Furthermore, there is some evidence that using incentives can actually reduce nonresponse bias in some situations by bringing in a more representative set of respondents (Castiglioni & Pforr, 2007; Singer, 2002; Singer, 2006;). This may be particularly effective in reducing nonresponse bias due to topic saliency (Groves et al., 2006).

4. **Burden on respondent:** There is a particular burden on participants who have recently had a baby because they may need to find specialized childcare. This incentive is designed to help offset participant burden.

197. Offering a monetary incentive at the proposed level will help ensure that respondents honor their commitment of fully participating in the focus group. Lower incentives could actually result in higher recruiting costs due to the need to over recruit by higher percentages (Krueger & Casey, 2009). To avoid these risks, CDC requests OMB approval to remunerate participants at the rate of $50 per focus group session and $25 per follow up interview.

198.

10. Assurance of Confidentiality Provided to Respondents

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200. The Privacy Office within NCBDDD has reviewed this submission and has determined that the Privacy Act does not apply. The screening questionnaire (see **Attachment 1**) to determine eligibility, the consumer focus groups (see **Attachments 3, 3a, 5, 5a, 7, 7a, 9, 9a, 11, 11a, and 13, 13a**), and the follow-up interviews (see **Attachments 4, 6, 8, 10, 12, and 14**) will include some questions on sensitive information such as planning for pregnancy and reproductive health. However, data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. Identifying information through the screener will be collected by the professional recruiting firm, but only for recruiting purposes and will not be attached to findings.

201. The only Information in Identifiable Form (IIF) that will be obtained is the participants' name, phone numbers, and mailing addresses for setting up interview appointments and mailing confirmation letters. This IIF will be maintained at Itracks in its proprietary files. These personal identifiers will not be linked to data. During the focus groups, only first names will be used. Focus groups will be transcribed for use by the RTI research team in developing a report. The digital audio tapes will be stored on a password protected share drive, accessible only to project staff. The recording will be destroyed at the end of the study, which is currently December 31, 2014.

202. Participation in the web focus groups is voluntary and participants will be advised that their responses will be treated in a secure manner and will not be linked to their names.

203. IRB Approval

204. CDC's Institutional Review Board (IRB) reviewed the study instruments and granted approval for the study due to minimal risk (see **Attachment 15**). The study was approved by the IRB on August 7, 2014. Activity is research involving human subjects, but CDC involvement does not constitute "engagement" in the research. CDC will not interact with individuals for research purposes and CDC will not obtain IIF, only de-identified data.

205.

11. Justification for Sensitive Questions

206. The purpose of this study is to conduct formative research with women of childbearing age (18–44) to assess their knowledge, awareness, beliefs, and access to information about medication use during pregnancy. Specifically, our research will focus on learning how women with chronic or acute conditions make decisions about medication use during pregnancy, including what sources of information they identify as credible. The screening questionnaire (see **Attachment 1**) to determine eligibility, the consumer focus groups (see **Attachments 3, 3a, 5, 5a, 7, 7a, 9, 9a, 11, 11a, and 13, 13a**), and the follow-up interviews (see **Attachments 4, 6, 8, 10, 12, and 14**) will include some questions on sensitive information such as planning for pregnancy and reproductive health. However, data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. Identifying information through the screener will be collected by the professional recruiting firm, but only for recruiting purposes and will not be attached to findings.

12. Estimates of Annualized Burden Hours and Costs

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208. For the focus groups, it is estimated that 144 respondents will have to be screened in order to recruit 72 participants. Each screening will take approximately 10 minutes. The estimated response burden for the screening process is 24 hours.

209. The focus groups will have an average of 12 participants each. Six focus groups will be conducted in virtual chat sessions with a total of 72 participants. At the beginning of each focus group, participants will be asked to complete a consent form (see **Attachments 2, 2a**).The informed consent will take 5 minutes to complete; the focus group discussion using the moderator's guide (see **Attachments 3, 3a, 5, 5a, 7, 7a, 9, 9a,**

11, 11a, and 13, 13a) will take 90 minutes to complete. All focus group activities will have a total burden of 138 hours.

210. We will conduct follow-up phone interviews (see **Attachments 4, 6, 8, 10, 12, and 14**) with 12 participants (two from each of the six groups). The interviews are expected to take 30 minutes for a total of 6 burden hours.

211. **Exhibit A.12.A Estimated Annualized Burden Hours**

212. **Type of Respondent**	213. 214. **Form Name**	215. **No. of Respondents**	216. **No. of Responses per Respondent**	217. **Average Burden per Response (in hours)**	218. **Total Burden Hours**
219. Women age 18-44 who plan to become pregnant/ had a baby within the last year 220.	221. 222. 223. 224. Screening Questionnaire for Consumers 225.	226. 144	227. 228. 1 229.	230. 231. 10/60 232.	233. 24
234. Women age 18-44 who plan to become pregnant/ had a baby within the last year	236. Virtual Focus Group (VFG) Focus Group Consent	237. 72	238. 1	239. 5/60	240. 6

235.					
241. Women age 18-44 who plan to become pregnant/ had a baby within the last year	242. Group 1- VFG Moderators Guide - pain	243. 12	244. 1	245. 90/60	246. 18
247. Women age 18-44 who plan to become pregnant/ had a baby within the last year	248. Group 2 – VFG Moderators Guide - Depression	249. 12	250. 1	251. 90/60	252. 18
253. Women age 18-44 who plan to become pregnant/ had a baby within the last year 254.	255. Group 3 – VFG Moderators Guide - Asthma	256. 12	257. 1	258. 90/60	259. 18
260. Women age 18-44 who plan to become pregnant/ had a baby within the last year 261.	262. Group 4- VFG Moderators Guide – Postpartum Acute Med	263. 12	264. 1	265. 90/60	266. 18
267. Wo	269. G	270.	271.	272.	273.

men age 18-44 who plan to become pregnant/ had a baby within the last year 268.	roup 5 – VFG Modera tors Guide – Postpar tum Depress ion	12	1	90/60	18
274. Wo men age 18-44 who plan to become pregnant/ had a baby within the last year 275.	276. G roup 6 – VFG Modera tors Guide- Postpar tum - Asthma	277. 12	278. 1	279. 90/60	280. 18
281. Wo men age 18-44 who plan to become pregnant/ had a baby within the last year 282.	283. F ollow-up Teleph one Intervie w	284. 12	285. 1	286. 30/60	287. 6
288. **TO TAL** 294.	289.	290.	291.	292.	293. 144

295. The annualized cost burden is show in Table A.12.B. The mean hourly wage rate is based on the most recent (May 2010) National Occupational Employment and Wage Estimates for all occupations, published on the Bureau of Labor Statistics website which is $21.35.

296. See http://www.bls.gov/oes/current/oes_nat.htm#00-0000.

297.

298.

299. **ExhibitA.12.B. Estimated Annualized Cost to Respondents**

300. Type of Respondent	301. Form Name	302. 303. Number of 304. Respondents	305. 306. Total Annual Burden 307. (in hours)	308. Avg. Hourly Wage	309. 310. Total Respondent 311. Cost 312.
313. Women age 18-44 who plan to become pregnant/ had a baby within the last year	314. Screening for Consumers	315. 144	316. 24	317. $21.35	318. $512
319. Women age 18-44 who plan to become pregnant/ had a baby within the last year	320. VFG Focus Group Consent	321. 72	322. 6	323. $21.35	324. $128
325. Women age 18-44 who plan to become pregnant/ had a baby within the last year	326. Group 1- VFG Moderators Guide - pain	327. 12	328. 18	329. $21.35	330. $384
331. Women age 18-44 who plan to become pregnant/ had a baby within the last year	332. Group 2 – VFG Moderators Guide - Depression	333. 12	334. 18	335. $21.35	336. $384
337. Women age 18-44 who plan to	338. Group 3	339. 12	340. 18	341. $21.3	342. $384

300. Type of Respondent	301. Form Name	302. 303. Number of 304. Respondents	305. 306. Total Annual Burden 307. (in hours)	308. Avg. Hourly Wage	309. 310. Total Respondent 311. Cost 312.
become pregnant/ had a baby within the last year	– VFG Moderators Guide - Asthma			5	
343. Women age 18-44 who plan to become pregnant/ had a baby within the last year	344. Group 4- VFG Moderators Guide – Postpartum Acute Med	345. 12	346. 18	347. $ 21.35	348. $ 384
349. Women age 18-44 who plan to become pregnant/ had a baby within the last year	350. Group 5 – VFG Moderators Guide – Postpartum Depression	351. 12	352. 18	353. $ 21.35	354. $ 384
355. Women age 18-44 who plan to	356. Group 6 – VFG	357. 12	358. 18	359. $ 21.35	360. $ 384

300. Type of Respondent	301. Form Name	302. 303. Number of 304. Respondents	305. 306. Total Annual Burden 307. (in hours)	308. Avg. Hourly Wage	309. 310. Total Respondent 311. Cost 312.
become pregnant/ had a baby within the last year	Moderators Guide-Postpartum – Asthma				
361. Women age 18-44 who plan to become pregnant/ had a baby within the last year	362. Follow-up Telephone Interview	363. 12	364. 6	365. $ 21.35	366. $ 128
367. **Total**	368.	369.	370.	371.	372. **$ 3,072**

373.
374.

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

375. There will be no direct costs to the respondents other than their time to participate in each survey.

376.

14. Annualized Cost to the Government

377. The annualized cost of this project is estimated to be $90,950. Costs to the federal government ($16,950/yr) include labor costs for grant oversight and technical assistance. Grantee costs ($74,000/yr) include development of the instruments, recruitment and incentives, data collection, data analysis, and reporting of results. See Exhibit A.14.

378. **Exhibit A.14:** Estimated Annualized Cost to the Federal Government

379. **E**	380. **Expense Explanation**	381. **Annu**

xpense Type		al Costs (dollars)
382. Direct Costs to the Federal Government	383. Personnel 384. 385. Health Scientist-15 2.5% 386. Health Scientist-14 2.5% 387. Health Communication Specialist/Health Scientist-12 3.8% 388. Health Scientist-12 2.5% 389. Pharmacist-Commissioned Corps- 2.5% 390.	391. 392. 393. $ 4,415 394. $ 3,899 395. $ 3,996 396. $ 2,344 397. $ 2,296
398.	399. Subtotal	400. $16,950
401. Grant Expenses	402.	403. $74,000
404.	405. Total Annual Cost	406. $90,950

407. The personnel costs were calculated using the 2014 General Schedule http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2014/general-schedule/.

408.

15. Explanation for Program Changes or Adjustments

409. This is a new information collection request, therefore program changes and adjustments do not apply.

410.

16. Plans for Tabulation and Publication and Project Time Schedule

411. RTI team members will independently review and code transcripts from the six virtual groups and the 12 interviews in NVivo 10.0 qualitative analysis software. Transcripts from the groups and the interviews will be uploaded into one NVivo database so that patterns can be assessed across the entire data set. Two to three team members will examine participants' responses and code responses based on a predetermined coding structure. Once coding is completed, we will produce coding reports and identify trends across the groups and, when applicable, within the group segments.

412. The RTI analysis team will review transcripts and then analyze them using the following steps (adapted from Krueger & Casey, 2000):

413. 1. Assign each focus group and interview an identification number.

414. 2. Code the responses according to a set of pre-developed codes that represent key constructs.

415. 3. Develop and assign emergent codes for responses that do not fit the preexisting coding scheme.

416. 4. Using these pre-established and emergent codes, identify the key themes and determine the degree of consensus or discordance with a particular view; the goal of a focus group is to focus on what the group thinks, not on what the individual thinks.

417. 5. In a cross-group matrix, organize the key themes in accordance with the research question most closely addressed by the group, noting particularly relevant quotes.

418. 6. Using the cross-group matrix, identify cross-cutting themes and areas lacking consensus.

419. These steps are designed to systematically summarize responses from the individual level to the group level and then to the cross-group level in an objective and transparent manner.

420. We will ensure that the data are coded consistently and objectively by double-coding one to two transcripts, or until interrater agreement of 90% is achieved. We will also seek the input of Centers for Disease Control and Prevention (CDC) technical officers in interpreting the data (Steps 4 and 6) to further enhance the objectivity of the analytic process.

421. Krueger and Casey further recommended that the following questions be asked as part of the analysis:

- What was known that was confirmed or challenged by the focus group data?
- What was suspected that was confirmed or challenged by the focus group data?
- What was new that was not previously suspected?

422.....
423.....**Exhibit A.16**: Project Time Schedule.
424.....

425. **Activity** 426.	427. **Time Schedule**
428. Begin recruitment for	429. Upon OMB approval

virtual focus groups	
430. Conduct six virtual focus groups	431. 3 weeks after OMB approval
432. Conduct follow-up interviews	433. 5 weeks after OMB approval
434. Begin two-week Phase 1 Pre-implementation Survey period	435. 5 weeks after OMB approval
436. Begin analyzing data and compiling reports	437. 7 weeks after OMB approval

438.....

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

439. The OMB Expiration Date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

440. There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

441. **References**

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