

**Minority HIV/AIDS Research Initiative (MARI) Project:  
Empowering Latinas to Lash Out Against AIDS (ELLAS)**

**Generic Information Collection Request under 0920-0840**

**Supporting Statement  
Part A**

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47. A. **JUSTIFICATION**

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49. A.1 **Circumstances Making the Collection of Information Necessary**

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51. The Centers for Disease Control and Prevention proposes to conduct a formative research study that will provide vital information to facilitate HIV prevention efforts with Latinos/Latinas in the United States.

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53. Latinos/Latinas have become the largest minority ethnic group in the United States, and like Blacks, they are disproportionately affected by HIV/AIDS. In the U.S., perinatal HIV transmission occurs disproportionately among Latino and Black populations.

54. Routine HIV testing in pregnancy has been shown to reduce mother-to-child transmission of HIV. Recent increases in Latino population growth have created challenges in understanding whether pregnant Latina patients are being routinely offered HIV counseling and testing and whether they may accept or decline to be tested, if offered. The purpose of this project is to explore strategies that pregnant Latinas and providers use to communicate about perinatal HIV testing. Data regarding best practices learned from the surveys, interviews and focus groups with Latinas and their providers will be used to help facilitate the development of culturally and linguistically appropriate perinatal HIV prevention materials for pregnant Latinas. These data will help ensure that culturally and linguistically appropriate tools are developed as part of the CDC portfolio of effective HIV prevention interventions for Latinos/Latinas. In addition, the previously untested Spanish-language version of "One Test/Two Lives" communication that explains and encourages HIV testing among pregnant women will be evaluated by the Spanish-speaking participants during this study.

55.

56. Specifically, the types of information collection activities are:

- 1) In Phase 1, after screening for eligibility (Attachment 1a), 220 pregnant Latinas will be surveyed by ACASI (Attachment 1b). The usability of electronic data collection

methodology is new for HIV prevention formative research with this population. The purpose of using this method for data collection is to develop new methods that can be used for HIV prevention with a large Spanish-speaking population in the context of rapidly-evolving technology-based surveys and communications. Data are not yet available regarding the use and effectiveness of these technology-based surveys and communications with this population of mostly Spanish-speaking Latinas. Additionally, these technologies will enhance CDC's HIV prevention portfolio by adding culturally-appropriate and relevant materials for Spanish-speaking populations. The electronic means of data collection also will reduce the burden of future data collections by establishing this approach as a valid one for data collection with this population for HIV prevention efforts.

- 2) In Phases 1 and 2, qualitative interviewing will occur with the pregnant or postpartum Latinas (6 FG in Phase 1; 1 FG in Phase 2; Attachments 1d and 1e) and their obstetrical providers (individual interviews with 12 providers in Phase 1, and 6 providers in Phase 2; Attachments 1c and 1f). The HIV prevention and testing questions will provide context to inform the development or tailoring of culturally appropriate materials for Latinos/Latinas as part of the CDC portfolio of HIV prevention interventions.
- 3) In Phase 2, both Latinas and obstetrical providers will participate in cognitive individual and focus group interviews to test the HIV prevention materials that are developed/revised from the responses in Phase 1 (Attachments 1e and 1f). This cognitive component will also allow for feedback that will help improve the Spanish-language One Test/Two Lives CDC HIV prevention program, so that it can be widely disseminated within CDC's portfolio of HIV prevention materials for Latinos/Latinas in the United States.

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60. **A.1.2 Privacy Impact Assessment**

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62. The grantee, University of South Carolina, will collect information in identifiable form (IIF). Information for the quantitative survey of individuals will be collected electronically using audio computer-assisted self-interview (ACASI) at the obstetrical visit location sites. The local study staff will collect IIF, such as names and contact information for possible later participation in a survey, interview, or focus group. Other IIF collected include age, race, and ethnicity. Contact information will be destroyed

following the appointment for participation in an interview, survey, or focus group. All data will be identified by code numbers. No quantitative surveys or audio transcripts will contain participant names. The only link to respondents' names will be consent forms, to be housed in a locked file cabinet separate from all data forms. Surveys will be labeled with a unique pre-assigned code to identify the computer-stored data. Interviews and focus groups will be digitally recorded. At the end of each focus group session and interview, recordings will be transcribed and the transcripts will be stored in the password-protected Program Coordinator's computer. The computer with the stored data will be kept in a locked office, with the key accessible to only the Program Coordinator and Primary Investigator (PI). Only ID numbers will be used to identify the participants. No names will be attached to any of the recordings or transcripts. Any names used during focus group sessions and interviews will be replaced during transcription by initials to prevent unintended disclosure. Transcripts will be accessible only to study investigators responsible for data analysis and the Program Coordinator.

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64. CDC will not receive any IIF. If there were a need to send data to CDC for review, all IIF collected by local partners would be unlinked or stripped from the data base that is submitted to CDC.

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**68. A.1.3 Overview of the Data Collection System**

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70. The proposed study will have two phases. During Phase 1, data will be collected through pregnant/postpartum Latina ACASI surveys, provider interviews and focus groups with pregnant and/or postpartum Latinas at obstetrical visit locations. Phase 2 will consist of provider interviews and focus groups (FG) with Latinas to assess culturally tailored HIV prevention and testing materials for pregnant Latinas, including CDC's One Test/Two Lives prenatal HIV testing Spanish-version materials and messages (which have not yet been tested among Spanish speaking populations).

71.

72. Specifically, the types of information collection activities are:

- 1) In Phase 1, after screening for eligibility (Attachment 1a), 220 pregnant Latinas will be surveyed by ACASI (Attachment 1b). The usability of electronic data

collection methodology is new for HIV prevention formative research with this population. The purpose of using this method for data collection is to develop new methods that can be used for HIV prevention with a large Spanish-speaking population in the context of rapidly-evolving technology-based surveys and communications. Additionally, these technologies enhance CDC's projects and reduce the burden of future data collections.

- 2) In Phases 1 and 2, qualitative interviewing will occur with the pregnant or postpartum Latinas (6 FG in Phase 1; 1 FG in Phase 2; Attachments 1d and 1e) and their obstetrical providers (individual interviews with 12 providers in Phase 1, and 6 providers in Phase 2; Attachments 1c and 1f). The HIV prevention and testing questions will provide context to inform the development or tailoring of culturally appropriate materials for Latinos/Latinas as part of the CDC portfolio of HIV prevention interventions.
- 3) In Phase 2, both Latinas and obstetrical providers will participate in cognitive individual and focus group interviews to test the HIV prevention materials that are developed/ revised from the responses in Phase 1 (Attachments 1e and 1f). This cognitive component will also allow for feedback that will help improve the Spanish-language One Test/Two Lives CDC HIV prevention program, so that it can be widely disseminated within CDC's portfolio of HIV prevention materials for Latinos in the United States.

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75. **A.1.4 Items of Information to be Collected**

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77. The ACASI survey conducted among Latinas will collect data regarding:

- Acceptability of the computerized data collection process
- Knowledge, beliefs and attitudes about HIV/AIDS transmission,
- Intention to take an HIV test,
- Knowledge about perinatal HIV testing being offered and administered,
- Perception of their health care providers' support for perinatal HIV testing,
- Feelings of depression.

78.

79. Pregnant/Post Partum Latina Focus Groups will collect data regarding:

- 80.
- the sources pregnant Latinas prefer to use to obtain messages on HIV testing and education,
  - barriers to accessing health care services and to relating to health care providers regarding HIV testing
  - HIV transmission and testing knowledge, attitudes and beliefs
  - if and how the opt-out testing approach is being used with pregnant Latinas,
  - whether pregnant Latinas perceive differential treatment from health care providers compared to other racial/ethnic groups.
  - Opinions regarding culturally tailored materials for pregnant Latinas.

81.

82. Health care provider interviews will be used to collect information on the care providers' perception of:

- what occurs during prenatal visits,
- any barriers or facilitators they may have encountered in communicating with their Latina patients,
- support for prenatal HIV testing,
- culturally tailored materials for pregnant Latinas.

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85. **A.1.5 Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age**

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87. This information collection does not involve websites or website content directed at children under 13 years of age.

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90. **A.2. Purpose and Use of Information Collection**

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92. The purpose of this information collection includes the following:

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94. **A.2.1 Qualitative interviewing for surveillance, research, and intervention methods and material development.**

95.

96. The purpose of the "Minority HIV/AIDS Research Initiative (MARI) Project: Empowering Latinas to Lash Out Against AIDS (ELLAS)" is to conduct formative research for developing new tools and methodologies that use qualitative interviewing methods to identify appropriate project methods, intervention content and delivery, and instrument domains and questions as they relate to HIV testing for

pregnant Latinas. Qualitative interviews will be conducted in focus groups (with the Latina pregnant or postpartum participants) and individually (with the health care provider participants), using standardized methods. The information collected from this study will be used to develop innovative and culturally relevant intervention materials, data collection instruments and research methods for current and future projects to increase HIV testing efforts among pregnant Latinas. The types of data collection activities used are the following:

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99. **A.2.4 Usability testing of technology-based instruments and materials**

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101. This research examines how questions, instructions, and supplemental information are presented on computer instruments (e.g., Computer Assisted Personal Interview (CAPI), Computer Assisted Self Interview (CASI), or Web-based instruments), and investigates how the presentation affects the ability of users to effectively utilize these instruments. Specifically, this data collection will use computer-based survey of individuals with the pregnant Latinas to explore how questions and instructions are presented on computer instruments, and will investigate how the computer presentation affects the ability of users to effectively utilize these instruments for future research within this population. This data collection will use the audio portion of the ACASI computer surveys to explore the appropriate Spanish language translations and dialects for this type of research with this population.

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104. **A.2.6 Testing of Communication Mental Models**

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106. The purpose of this data collection is to develop and test mental modeling methodologies. The information that will be collected during the Phase 2 focus groups and interviews with the Latinas and health care providers will be used to revise, augment or finalize communication campaign platforms (CDC's One Test/Two Lives-Spanish language materials; English-language materials are included with Attachment 1e) and systems within the context of the audiences' sense of reality for antenatal HIV testing with Latinas.

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

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111. The use of an ACASI system will reduce the time need to complete the surveys of individuals and will thereby reduce the burden on the public. Electronic reporting has advantages for ensuring respondent privacy and streamlining the data collection process. The computer programs will allow participants to select for an audio assistant to read the questions and answer options in either English or Spanish, depending on their preference. Interviews and focus groups will be digitally recorded and transcribed.

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

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116. NCHHSTP has verified that there are no other federal collections that duplicate the data collection tools and methods included in this request.

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119. **A.5. Impact on Small Businesses and Other Small Entities**

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121. No small businesses will be involved in this data collection.

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**123.**

124. **A.6. Consequences of Collecting the Information Less Frequently**

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126. The activities involve a one-time collection of data. There are no legal obstacles to reducing the burden.

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**128.**

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

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131. This request fully complies with the regulation 5 CFR 1320.5.

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**133.**

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

135.

136. A Federal Register Notice for the generic clearance 0920-840 was published on March 11, 2009.

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

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141. Project participants will be offered cash tokens of appreciation that will not exceed \$40 per person per hour.

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143. In Phase 1, Latinas who participate in the 30-minute survey of individual (ACASI) will receive a \$20 token of appreciation for their time. Latinas who participate in the 90-minute focus group will receive a \$20 token for their time. Obstetrical providers who participate in the interviews will receive a \$20 token of appreciation. In Phase 2, a group of Latinas (different from those who were part of Phase 1) will receive \$20 for their participation in a 60-minute cognitive focus group interview regarding the tailored materials. Providers who review the materials and are interviewed (30 minutes) will be given \$20 for their time. No one in the study will receive more than \$40 total in tokens of appreciation.

144.

145. This token is being offered to show appreciation for the time spent completing assessments and for participating in focus group and individual interview sessions. Through previously conducted research with this target population of Latinas and also with busy obstetrical health care providers, the investigators have determined that this level of token is the most reasonable amount to ensure participation and meet the goals of this information collection.

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147. While tokens of appreciation will be utilized for the assessments in this information collection, there is no intention to continue their use if these study materials are proven to be effective and widely adopted.

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**149.**

**150. A.10. Assurances of Confidentiality Provided to Respondents**

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153. To ensure data security, this contact information database will be kept separate from other data collected and in a password-protected file in the PI's locked office. All codes that link participants' name with ID numbers will be available only to the PI and Program Coordinator and kept in a locked cabinet. ACASI data will be downloaded weekly and stored on a secure, password protected computer. Procedures

to ensure quality control in the collection, verification, and documentation of data have been established and will be conducted by a Data Analyst/Programmer on the study staff in consultation with CDC Data Managers.

154.

155. Respondents will be told that no information in identifiable form will be available to or shared with the CDC. Analysis of the dataset will take place at the University of South Carolina. The information that will be collected in this project will be owned by the University of South Carolina. The University of South Carolina will be the only entity with access to the IIF and information collected. If any data is shared with CDC it will be de-identified and transferred securely to CDC.

156.

157. Prior to participating in any study activity, both the Latina pregnant and postpartum patients and the health care providers will be required to give consent. The consent forms (English and Spanish versions) are included as Attachment 2. Study purpose, risks and benefits will be explained to the participants, and they will have the opportunity to ask questions prior to signing. Participants and ELLAS staff will be asked to sign two identical consent forms. One of the signed consent forms will be kept in a locked cabinet separate from other databases in the locked PI's office and the other will be given to the participant.

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159. Contact information forms will be destroyed (via shredding) within three years after completion of the data analysis, or sooner if appropriate.

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**161.**

**162. A.11. Justification for Sensitive Questions**

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164. During screening for eligibility, participants are asked sensitive questions about race, ethnicity, pregnancy status, and HIV status. These sensitive questions are necessary to determine eligibility for the study, because the study's purpose is to understand more about antenatal testing for pregnant Latinas and also to determine if using computer-based technology is an appropriate method to gather information to develop appropriate antenatal HIV prevention materials for this population.

165.

166. During the surveys, sensitive questions include information about country of birth, health insurance status, income, and HIV knowledge. These questions are important to

help us understand potential barriers and/or facilitators for HIV testing for pregnant Latinas. This information is necessary to characterize the study population. Knowledge of respondent characteristics is needed to develop culturally appropriate HIV prevention materials for pregnant Latinas as part of CDC's portfolio of effective HIV prevention tools.

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168. In no case will a participant's social security number be obtained by agency staff.

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171. **A.12.Estimates of Annualized Burden Hours and Costs**

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173. **A.12.A. Estimated Annualized Burden Hours**

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175. There are two types of respondents: 1) Latina pregnant or postpartum women (general public), and 2) obstetrical health care providers. Study staff will screen approximately 250 pregnant or postpartum Latinas during the first year. The 250 Latinas will take part in a 5-minute screening interview to assess study eligibility; approximately 220 Latina pregnant or postpartum women are expected to participate in the survey of individual (ACASI), which will take 30 minutes. Forty-two Latinas will participate in a focus group for 1.5 hours. The 18 total health care providers will take part in a 45-minute individual interview process.

176.

177. During the first year after OMB approval, all data collection will occur: 1) 220 pregnant or postpartum participants will be surveyed using ACASI once; 2) 36 women who complete the ACASI survey will participate in focus groups (6 women per FG); 3) 12 obstetrical health care providers will be surveyed individually; 4) 6 pregnant or postpartum Latinas will participate in a FG to provide feedback on newly-developed antenatal HIV prevention materials or revised One Test/Two Lives Spanish-language materials, and 5) 6 obstetrical health care providers will be surveyed individually to give their feedback on newly-developed materials or revised One Test/Two Lives Spanish-language materials.

178.

**179. Exhibit A.12.A Annualized Burden Hours**

180. Type of Respondent	181. Form Name	182. Number of Respondents	185. Number of Responses per Respondent	189. Average Hours per Response	192. Total Response Burden (Hours)
196. General public	197. Screener	198. 250	199. 1	200. 5/60	201. 21
202. General public	203. Survey of Individual (ACASI)	204. 220	205. 1	206. 30/60	207. 110
208. General public	209. Group 210. Group 211. Interview	212. 42	213. 1	214. 1.5	215. 63
216. Health care providers	217. Individual 218. Interview	219. 18	220. 1	221. 45/60	222. 14
<b>223. Total</b>	<b>224.</b>	<b>225.</b>	<b>226.</b>	<b>227.</b>	<b>228. 208</b>

229.

230.

**231. A.12.B. Estimated Annualized Costs**

232.

233. The annualized costs to respondents are described in Exhibit A.12.B. The estimates of hourly wages were obtained from the Department of labor (Bureau of Labor Statistics Wage Data (<http://www.bls.gov/bls/wages.htm>). Different cost rows were added to reflect that both general public (pregnant or postpartum Latinas) and health care providers are included. The total

anticipated annual cost to participants for collection of information in this project will be \$5,045.

234.

**235. Exhibit A.12.B. Annualized Cost to Respondents**

236.

237. Type of Respondent (Form Name)	238. Total Burden Hours	239. Hourly Wage Rate	240. Total Respondent Costs
241. General public (Screeners)	242. 21	243. \$20.23	244. \$425
245. General public 246. (Survey of individual (ACASI))	247. 110	248. \$20.23	249. \$2,225
250. General public 251. (Group Interview)	252. 63	253. \$20.23	254. \$1,275
255. Health care providers 256. (Individual Interview)	257. 14	258. \$80.00	259. \$1,120
<b>260. Total</b>	<b>261. 208</b>	<b>262.</b>	<b>263. \$5,045</b>

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266.

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

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269. There are no other costs to respondents or record keepers.

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272. A.14. Annualized Costs to the Government

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274. This activity will involve participation of one CDC project officer who will assist with project design, obtaining IRB and OMB approvals, and providing project oversight. A contracting data manager is involved to provide support and maintenance for the ACASI QDS program that will be used during data collection and analysis. A student research assistant will assist with literature reviews. Travel expenses include six site visits.

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279. Expense Type	280. Expense Explanation	281. Annual Costs (dollars)
283. Direct Costs to the Federal Government	284. CDC Project Officer (Commissioned Corps, 0-5, 0.25 FTE)	285. \$37,000
286.	287. CDC Research Assistant (50%)	288. \$3,000
289.	290. CDC Site Visit Travel (6 trips)	291. \$7,000
292.	<b>293. Subtotal, direct costs to the government</b>	<b>294. \$47,000</b>
295. Cooperative Agreement or Contract	296. Cooperative Agreement to the University of South Carolina	297. \$188,550

ct Costs			
298.	299. Contractor Data Manager/QDS Support (GS-10 equivalent; 0.35 FTE)	300.	\$35,000
<b>301.</b>	<b>302. Subtotal, cooperative agreement or contract costs</b>	<b>303.</b>	<b>\$223,55 0</b>
<b>304.</b>	<b>305. TOTAL COST TO THE GOVERNMENT</b>	<b>306.</b>	<b>\$270,55 0</b>

307.

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**309.**

**310. A.15.Explanation for Program Changes or Adjustments**

311.

312. Not applicable - request is for a sub-collection under a generic approval.

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**314.**

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

316.

317. Data collection will be completed during the first year after OMB approval is granted. Phase 1 data collection will be completed by 5 months after approval. Phase 2 of data collection will be completed by 10 months after approval. Data analysis will be completed by 11 months after OMB approval. Report of findings will begin 12 months after OMB approval.

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**323. Exhibit 16.A. Project Time Schedule**

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<b>325.</b>	<b>326. Activity</b>	<b>327.</b>	<b>328. Time Schedule</b>
329.	Phase 1 data collection with general public and providers	330.	1-5 months after OMB approval
331.	Phase 2 data collection with general public and providers	332.	10 months after OMB approval
333.	Data analysis	334.	11 months after OMB approval
335.	Report of findings	336.	12 months after OMB approval

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**339.**

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

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342. OMB Expiration Date will be displayed.

343.

**344.**

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

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**347.** There are no exceptions to the certification.