Request for determination as an expedited collection under 0920-0840 "Formative and Tools Development"

Submit to nchhstp ombmailbox@cdc.gov

For NCHHSTP to conduct formative research for developing new tools and methodologies related to research on HIV/AIDS, STD, TB, and viral hepatitis. Short term qualitative interviewing and cognitive research techniques to develop scientifically valid and population-appropriate methods, interventions, and instruments.

Project Title: Pathways: Qualitative Interviews with Post-Partum Women Associated with Congenital Syphilis Cases (Case Mothers)

Requestor name and title:	Jennine Kinsey, Public Health Advisor
Division/Branch	Division of STD Prevention (DSTDP), Social and Behavioral Evaluation Branch (SABRE)
Phone number and email ID	404-639-6339; ire0@cdc.gov
Date of request	March 12, 2019
Dates of activity	April 1, 2019-March 31, 2019
Cost of Activity	$150,000.00
Funding Mechanism #: (FOA, RFTOP and or PN#)	CDC-RFA-OT13-1302
a. Contract __ b. Grant __X_ c. Cooperative Agreement ___d. Intramural ___ e. Other _____	
Is activity affected by existing OMB Approved ICR	No

Justification of Generic Use (Please provide a brief summary of the project and explain how your proposed activity fits under the scope of the Generic):

Please do not exceed 3-5 sentences for each heading. Please keep in mind that all data collections under this Generic must be completed in 1 year. It is the project officer's responsibility to read the Supporting Statement A of the Generic to ensure the project meets the scope outlined in the Generic.

Purpose / Goals of the project:	• The goal of this qualitative project is to better understand and identify factors that result in deviations from the "ideal" pregnancy narrative, as well as factors that are protective,

	supportive, or that appear to facilitate access to and use of timely and adequate prenatal care and syphilis diagnosis and treatment during pregnancy. We will 1) document women associated with congenital syphilis (CS) cases (case mothers) recollections of and perspectives about their pregnancy and prenatal care experience, 2) attempt to identify potential protective or supportive factors that would facilitate care and reduce the risk of CS, and 3) identify strategies to reach vulnerable women and increase awareness of the risks of CS during pregnancy.
Application/ Use of the project:	Findings from the interviews will help increase STD program capacity to reach women at risk for congenital syphilis (CS), and will prevent CS cases by identifying strategies for improving outreach and education to women at risk for CS.
Methods: (# of participants, recruitment, screening, sampling, sites, etc.)	• Data will be collected from sixty (60) semi-structured, 90-minute long, in-person qualitative interviews using a timeline elicitation method. Data will be collected from case mothers in three CDC-funded jurisdictions: the states of California and Florida and the metropolitan statistical area (MSA) of Chicago.The number of interviews to be conducted in each site will be based on weighted averages related to disease burden, but will be approximately 20 per location. Qualitative coding and thematic analysis of 60 in-depth interview transcripts using computer-assisted qualitative data analysis software Nvivo 11.
Anticipated results:	This study does not propose a hypothesis as it employs a descriptive, exploratory approach.
Cost to Government	$150,000.00

	Yes	**No**
1. The information collection will be limited to no more than 12 months.	**X**	
2. The purpose of the data collection is to… (check all that apply)		
Qualitative interviewing for surveillance, research, and intervention methods and material development	X	
Cognitive interviewing for development of specific data collection instruments		
Research on the effects of alternative instrument designs		
Research on cognitive aspects of non-response		
Respondent perceptions of enrollment procedures		

General methodological research		
Usability testing of technology-based instruments and materials (can be quantitative)		
Field testing of new methodologies and materials		
Testing of communication mental models		

3. The data collection will use the following methods (check all that apply)

	Yes	**No**
Qualitative interviewing* (Focus groups and/or individual)	X	
Cognitive interviewing		
Cognitive aspects of non-response*		
Quantitative interviewing (e.g., surveys or pilots) *		
Surveys including CAPI/CASI, ACASI, web-based surveys *		
Social marketing approaches		

*If this collection involves cash incentives the maximum allowed by OMB is $40 per hour not to exceed $80 per person or institution. Must have strong justification for use of an incentive.

4. Does this new collection require IRB approval? Yes

5. If yes, has the approval letter been issued? Yes

Determination basis

For use by the NCHHSTP PRA Clearance Coordinator