Clinic Context Matters Study

Supporting Statement A

OMB No. 0920-1058

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47. *A*. JUSTIFICATION

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49. A.1. <u>Circumstances Making the Collection of Information</u>

50. <u>Necessary</u>

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52. The Centers for Disease Control and Prevention (CDC), requests a 3-year approval for a new data collection entitled, "*Clinic Context Matters Study*". The collection will look at the characteristics of respondents and the characteristics, knowledge, attitudes and practices of the clinical practice staff as they relate to the introduction of a new clinical intervention (PrEP) in their clinics.

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54. The daily use of specific antiretroviral medications by persons without HIV infection, but at high risk of sexual or injection exposure to HIV, has been shown to be a safe and effective HIV prevention method. The Food and Drug Administration approved the use of Truvada® for preexposure prophylaxis (PrEP) in July 2012 and PHS has issued guidelines for its use. With approximately 50,000 new HIV infections each year, increasing rates of infection for young MSM, and continuing severe disparities in HIV infection among African-American men and women, incorporation of PrEP into HIV prevention is important. However, as a new prevention tool in very early stages of introduction and use, there is much we need to learn about how to implement PrEP in a real world setting.

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56. CDC is authorized to collect the data described in this request by Section 301 of the Public Health Service Act (42 USC 241). A copy of this enabling legislation is provided in **Attachment 1**.

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58. A.2. <u>Purpose and Use of Information Collection</u>

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60. The goal of the proposed information collection is to learn about clinician's knowledge, attitudes, and practices related to a new intervention (PrEP) during the period of its initial introduction in their clinics. Because PrEP is new, and highly effective, additional efforts to inform clinicians, and to design tools and methods to support its safe and effective delivery in clinical settings are critical. The knowledge gained will be used to refine

measurement instruments and methods, develop training and educational resources and tools for use by CDC/DHAP (Division of HIV/AIDS Prevention)-funded partners, and other organizations supporting delivery of PrEP in clinical settings. The results of this survey may be shared by presentation at scientific meetings, distribution to technical assistance providers for clinical HIV prevention partners, and publication of a report on a CDC website or in a journal.

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

The survey will be created using the Survey Monkey platform, which is extremely user friendly. Most of the questions are closed ended questions and require little effort to answer- often just a simple click on the device. When participants are finished with the survey, they simply click “submit” and they are finished.

A.3.1. Overview of the Data Collection System

Surveys will be conducted with Survey Monkey, an online survey tool that has received information security clearance for the collection of data by CDC.

A. 3.2. Items of Information to be Collected

Surveys will collect items of information related to: professional roles and demographic characteristics of respondents, clinical practice characteristics, knowledge, attitudes and practices related to introduction of a new clinical intervention (PrEP) in their clinics.

A.3.3. Identification of Websites and Website Content Directed at Children Under 13 Years of Age

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

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

Literature searches were conducted to identify duplicate information collections. No similar information is currently available for the purposes of this study. As far as we know, this information collection does not duplicate any existing efforts. This study will provide us with an understanding of the knowledge, attitudes, and organizational factors related to pre-exposure prophylaxis (PrEP) and its provision by clinicians at local clinics over time and an assessment of the utility of new measures developed or adapted to collect this information.

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

No impact on small business and other entities has been identified or is anticipated.

A.6. Consequences of Collecting the Information Less Frequently

If funding allows, the survey will be conducted once a year for 3 years. For some descriptive analyses, information will be collapsed across the three years but for attitudinal and knowledge measures, responses will be compared across the years for trend, using statistics appropriate to small cell sizes where indicated. If the survey were conducted less frequently, then we would not be able to assess changes over time among the clinicians. These changes over time are key to determine what types of resources need to be invested in assessing and addressing knowledge, attitudes, practices, and organizational factors related to pre-exposure prophylaxis and its provision at local clinics.

A.7. Special Circumstances Relating to 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

A 60 day federal register notice (**attachment 2**) to solicit public comments was published in the Federal Register on 08/11/2014, Volume 79, Number 154, and Page number 46827. One non-substantive public comment was

received and is included in **attachment 5**. The standard courtesy reply was sent in response to the public comment. No efforts to consult outside agencies were made.

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

Respondents will not be paid for survey participation.

A.10. Assurances of Confidentiality Provided to Respondents

No personally-identifiable information is collected. Survey responses cannot be linked to the individual respondent.

A.10.1. Privacy Impact Assessment

The clinic survey will be programmed (in Survey Monkey) for administration online to be accessed using a tablet, office, or home computer. The survey will take about 30 minutes to complete. Each clinician will be assigned an ID number (by their clinic) for completion of the online survey. No personal identifiers will be collected.

A.11. Justification for Sensitive Questions

A few demographic questions may be considered sensitive (i.e., race, age, sexual orientation) but are essential for understanding the population surveyed in relation to the population being provided PrEP.

A.12. Estimates of Annualized Burden Hours and Costs

This information collection will be collected once per year for three years. Potential respondents will receive an email inviting them to participate with a URL to the consent form and survey (**attachment 3**). There is no burden associated with the invitation other than reading the invitation. Respondents will consent once they access the link to the survey. The consent form and survey (**attachment 4**), is estimated to be 88 burden hours for the 175 respondents who will provide one 30-minute response per year.

124. Exhibit 12.A. Annualized Burden Hours

125. Type of Respondent	126. Form Name	127. 128. Number of 129. Respondents	130. 131. Number of 132. Responses per 133. Respondent	134. 135. Average Hours 136. Per Response	137. 138. Total Response 139. Burden 140. (Hours)
Clinician	Clinician Consent and Interview Att 4	141. 200	142. 1	143. 30/60	144. 100
145. Total	**146.**	147.	148.	149.	**150. 100**

151.

152. 12.B. Estimated Annualized Burden Costs

153. The annualized costs to the clinician respondents are described in Exhibit A.12.B. To estimate the participant costs, the hourly wage rate ($90.00) for general internists was used from the United States Department of Labor Statistics May, 2013 (http://www.bls.gov/oes/current/oes_nat.htm).

154. Exhibit 12.B. Annualized Cost to Respondents

155. Respondent	156. Form Name	157. Total Burden Hours	158. Hourly Wage Rate	159. Total Respondent Cost
Clinicians	Clinician Consent and Interview Att 4	160. 100	161. $ 90.00	162. $9, 000.00
163. Total	**164.**	**165.**	166.	**167. $9, 000.00**

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169. A.13. Estimates of Other Total Annual Cost Burden to

170. **Respondents and Record Keepers**

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There are no costs to respondents other than their time.

A.14. Annualized Costs to the Federal Government

The annualized cost to the government is estimated to be $34,700 per year for percentage of FTE time spent on the study. The total cost to the federal government for 3 years planned is $104,100.

Exhibit 14.A. Estimated Cost to the Government

Expense Type	**Expense Explanation**	**Total Costs per year (dollars)**
Project Officer	CDC Project Officer to monitor progress, review reports, etc. (GS-14 0.15) FTE)	$ 20,000
Statistician	CDC Statistician (GS 13 0.05 FTE)	$ 4,700
Data Manager	CDC Data Manager (GS 13 0.10 FTE)	$ 10,000
	Subtotal, Direct costs	**$ 34,700**
Total Costs to Government		**$ 34,700**

A.15. Explanation for Program Changes or Adjustments

A minor change is requested in the number of clinician respondents due to the addition of a second study clinic in a different part of Chicago to increase the racial/ethnic diversity of the clinic population. This results in 5 clinics rather than the original 4. Therefore the total annual number of clinicians surveyed increases from 175 to 200.

A nonsubstantial change is requested in the study sites because 2 of the

original clinics (in Newark and Houston) did not provide PrEP (the clinical intervention being studied) and they were replaced by clinics in 2 new cities (Washington DC and Jackson MS). The interview form needs to be adjusted to record clinic site of respondent for the current clinics.

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

Exhibit 16.A Project Time Schedule

Activity	Time Schedule
Administer survey	1-3 months after OMB approval and then annually for 2 additional years
Data analysis	4-6 months after OMB approval and then annually for 2 additional years

Survey results will be published in a peer-reviewed journal and presented at one or more conferences.

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

OMB Expiration Date will be displayed.

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

There are no exceptions requested.