1. Alexandra Balaji, PhD has replaced Kristina Bowles, MPH as the CDC project officer for "Multi-Site HIV Testing in Mental Health Settings (0920-08BL)." The contact information has been updated accordingly. *(ICR, page 1/page 22)*

2. OMB comment: How will results from this survey be translated into a "best practices" document? What data items/interview questions specifically inform "best practices" for HIV testing in community mental health settings? Analyses of which interview questions will be used to provide such recommendations? *(ICR, page 5)*

CDC response: Although the paragraph to which this comment refers is relevant to what will be learned from implementation of HIV testing in this study population, it is not specific to the information gained using the structured interview. We realize that this may be confusing and have therefore deleted the paragraph.

"Findings from the project will also provide guidance to mental health service providers about best practices for incorporating HIV testing (including the provision of HIV education, pre-test information, post-test information, and linkage of newly-identified HIV-positive persons to health and preventive care services) into the care they routinely offer to individuals with mental illness. Study findings will further be used as the basis to refine recommendations for offering HIV testing in community mental health settings in a manner which causes minimal impact on and disruption of their ongoing activities. The project also has the potential to reduce the incidence of new HIV infections by providing an effective HIV prevention intervention that contributes to a reduction in HIV risk for thousands of patients who undergo testing in these settings. This project will also have implications for the public health care system, in that it could significantly reduce intensive care and inpatient costs for patients who present at an advanced stage of HIV infection in these settings." *(ICR, page 5)*

3. OMB comment: What will the medical record data and Medicaid claims data information be used for? Also, please be sure to notify participants of this in the consent form. **(***ICR, page 5/page25)*

CDC response: Medical record data will be used to track service utilization prospectively for all study participants for approximately 6 months. In addition, for the three mental health settings in Philadelphia, Medicaid claims data will also be used to trace service utilization. The supplementary information about psychiatric diagnoses and clinical manifestations will further clarify the association between mental health and HIV testing. This information will also be used to assess whether or not persons who receive rapid HIV testing have greater mental health service utilization during the observation period.

Participants are notified in the consent form about the request to review their medical records and Medicaid claims data *(ICR, page 25)***.** We have also added a separate form authorizing release of medical records for use in this research which contains all the

required elements of valid authorization *(ICR, page 31)*. The version of this form to be used in the three Baltimore sites will be adjusted slightly since Medicaid data will not be collected at these locations. Due to the outlined modifications, we have *not* made the changes to the consent form regarding the authorization to review medical records originally requested by OMB. *(ICR, page 25)*

4. OMB comment: Why will the data be stored for 7 years specifically? Past that time, will any form of the data be retained, or will just reports of the study be retained? *(ICR, page 5)*

CDC response: Storing data for a period of 7 years is a standard practice for CDC research projects. Seven years provides researchers with ample time to complete research activities while not maintaining the data indefinitely. After this time period, only reports of the study will be retained. *(ICR, page 5)*

5. OMB comment: Is the structured interview part of an ongoing study? If not, please revise date. *(ICR, page 5)*

CDC response: The structured interview is not a part of an ongoing study so the dates indicated (2008-2011) have been deleted from the text. *(ICR, page 5)*

6. OMB comment: It is unclear how a "best practices" document will be drawn up from results from this survey. Questions in the interview seem targeted to describe the respondent's behaviors (e.g. drug use, sexual activity, health/screening behaviors, etc.), rather than about the process of testing, which would yield information about "best practices" for community mental health sites. *(ICR, page 6)*

CDC response: Similar to item 2 above, the findings referred to in this section of the ICR are not the information gained specifically from the structured interview but rather are related to the information gained from offering HIV testing. To clarify, we have removed the following statement:

"Since mental health facilities vary in their clients and services, findings from this study will further be used as the basis to refine recommendations for best practices to offer such testing in community mental health settings in a manner which causes minimal impact on and disruption of their ongoing activities." *(ICR, page 6)*

7. OMB comment: Please clarify how this study will inform health departments by adding, "in that this data may help document a need for HIV testing in mental health settings." (To the sentence that originally read: "Findings from this study will further inform state and city health departments in planning for HIV services in mental health

settings and for evaluating local care and prevention services for persons with severe mental illness.") *(ICR, page 6)*

CDC response: The following sentence has been adjusted to clarify how this study will inform health departments: "Findings from the implementation of this study will further inform state and city health departments in planning for HIV services in mental health settings and for evaluating local care and prevention services for persons with severe mental illness *in that these data may help document a need for HIV testing in mental health settings.*" *(ICR, page 6)*

8. OMB comment: Please add a clear discussion of exactly what this interview/questionnaire measures, as well as the limitations of this study. Please also state that such a discussion will be included in all presentations/publications of results. *(ICR, page 6)*

CDC response: We have added the following sentences:
"The structured interview will consist of questions on demographics, HIV risk behaviors, mental health symptoms, and HIV, STI and Hepatitis C testing history. Collection of this patient-level data will be used to characterize those who agreed to HIV testing. The limitations of this study are that the data are self-reported and therefore may have associated biases and/or inaccuracies. In addition, the study uses a convenience sample and therefore may not be generalizable to the mental health patient population as a whole. However, the results are likely to be representative of those individuals who can be reached for HIV testing within community mental health settings." *(ICR, page 6)*

"All presentations and publications of the data will include a discussion of the content of the structured interview and the limitations of the study." *(ICR, page 7)*

9. OMB comment: It is stated later that the expected response rate is 90%. If the expected response rate is high, there is no clear need for an incentive at all. Especially as recruitment and testing (for approximately 20 minutes) will be conducted on-site with people who have already traveled for an existing appointment, it is not expected that recruitment would be a problem without an incentive offered at all. Please remove incentive payment.

If however CDC has experience recruiting a similar population in similar circumstances for similar amounts of time, or can document such an occurrence, and response rates were low without an incentive payment, having some incentive could be justified. However, the justification would have to be why this particular sample of people would be difficult to reach, and why it would be difficult to get this group to consent to a 20-minute interview questionnaire on a site to which they had already traveled. (Justification based solely on other incentive amounts that were approved for other studies would not be sufficient.) *(ICR, page 9)*

Documentation? In these studies, how much time was asked of people with SMI? What "other means of motivation" were unsuccessful? Where these people interviewed/surveyed at a site to which they had already traveled? To justify any incentive amount, CDC would have to make a case for why such an amount is necessary given this particular situation, using documented information from previous studies or experience. (Again, using another study's incentive amounts as justification is not sufficient.) *(ICR, page 20)*

CDC response: To address these concerns, **Supporting Statement A, Section 9: Explanation of Any Payment or Gift to Respondents**, has been rewritten as follows:

"In order to increase response rates, persons approached will be offered $20 as an incentive for the time spent completing the structured interview. If local regulations prohibit cash incentives, equivalent incentives may be offered in the form of personal gifts, gift certificates, or bus or subway tokens. Persons who consent to be interviewed will be administered a structured interview (Attachment 3c), which will take approximately 20 minutes to complete. It should be emphasized that the incentive is being offered for participating in the structured interview component of the study. If the results from this study indicate that testing SMI patients is a strategy worthy of replicating in other locations, the structured interview would not be conducted and the incentive would not be required for HIV testing alone.

It is expected that with the $20 incentive, that the response rate for this study will be 90%. However, if the incentive is not offered, the response rate would likely drop below 50%. The anticipated effect of the $20 incentive is based on previous work by the principal investigator (PI) of this study, the experiences of other researchers working with similar study populations, and the practice of multiple prior CDC studies to provide incentives for the time being interviewed. Dr. Michael Blank, the PI for the current study, previously conducted a project entitled "Preventing AIDS through Health" (PATH), involving a similar study population as the current study. In this study, an incentive of $20 was offered to participants, resulting in a response rate of 90%. In addition, a number of other studies involving persons with SMI, substance abusers, and the homeless and economically disadvantaged have utilized incentives for a participant's time to increase response rates.[5, 11, 12] A study by Slomka and colleagues [13] on the perceptions of financial payment for research participation among African-American drug users in HIV studies found that participants viewed monetary compensation for research as an essential component of participation. In terms of the amount offered, less that $20 was considered ineffective as a recruitment tool and unfair to research participants. Finally, incentives have been used in multiple prior CDC studies for persons who agree to participate in interviews to help achieve adequate response rates. For example, a similar incentive was used in CDC's Supplement to HIV/AIDS Surveillance (SHAS) project (OMB 0920-0262, exp 06/30/2004). In SHAS, persons who agreed to participate in the interview were offered approximately $25 as compensation for their time." *(ICR, page 9)*

Supporting Statement B, Section 3, Methods to Maximize Response Rates and Minimize Nonresponse, has been rewritten as follows:

"Because the structured interview will take approximately 20 minutes to complete, to increase response rates, potential participants will be offered an incentive for the time required to complete the structured interview, which is intended to reduce the burden of this data collection. Participants will be provided an incentive of $20 in cash for participation in the interview, but not for HIV testing without the interview. If local regulations prohibit the use of cash, the equivalent amount may be offered in the form of personal gifts, gift certificates, or bus or subway tokens. As noted, the importance of the $20 incentive for participants' time is based on previous work by the PI of this study, the experiences of other researchers working with similar study populations, and incentives have been used in multiple prior CDC studies for persons who agree to participate in interviews. In addition, monitoring of response rates will be done through conference calls on a regular basis with the implementation sites, offering the opportunity to share additional strategies for improving response rates on an on-going basis."
(ICR, page 20)

Because we believe that providing $20 to participants who agree to be interviewed is justified, the following statement was *not* deleted from **Attachment 8: Model Patient Information and Consent Form**, as had been originally requested:

"You will receive $20 for completing the survey. If you agree to participate in the study, but change your mind and decide to not complete the survey, you will not receive $20."
(ICR, page 25)

10. OMB comment: Please use the term "private" in all consent documents. *(ICR, page 10/page26)*

CDC response: The requested change from "confidentiality" to "private" was *not* made as the project is covered under an assurance of confidentiality and CDC has been advised that confidentiality is the appropriate term to use in this case. In addition, all five reviewing IRB committees approved the consent document which included the term "confidential."

11. OMB comment: How will the data be used to improve HIV services to persons with severe mental illness? *(ICR, page 12)*

CDC response: We have added the following sentences to explain how the data will be used to improve HIV services to persons with severe mental illness:

"These data will be used to improve HIV services to persons with severe mental illness in two key ways. First, these data will be used to determine the proportion of persons testing positive for HIV among a sample of individuals receiving mental health services, thereby providing insight into the need for HIV testing and services in such settings. Second, these data can be used to evaluate the associations between HIV infection and

participants' characteristics, including reported psychiatric symptoms, reported sexual and drug-using risk behaviors, and chart abstracted psychiatric diagnoses." *(ICR, page 12)*

12. OMB comment: Why two waves of data collection? Will the first wave/group be compared to the second in any way? Are the two waves/groups expected to differ from each other in any way? *(ICR, page 13)*

CDC response: For clarification on the timeframe of data collection, we have added the following sentences:

"Although data collection will span two years, this time period represents a single data collection period. This time frame as well as the number of interviews projected is based on the estimated number of clients who would be eligible to be approached during a period of this length, the precision of estimates associated with a given sample size, and the time and resources available for this project." *(ICR, page 13)*

13. OMB comment: Because this is a questionnaire with only multiple choice questions, why is this offered as an interview at all? *(ICR, page 13) /* Do "personal interview," "interview instrument," "structured questionnaire" and "survey" all refer to the same thing? Please standardize language. *(ICR, page 19)*

CDC response: It was indicated during a call with OMB reviewers on 10/27/2009 that structured interview was the preferred term. Therefore, "structured interview" is now used throughout the ICR document.

14. OMB comment: Why was the following method selected for choosing participants – "The interviewer will choose patients based on the time they checked in for their appointment, beginning with those who have been in the waiting room the shortest period of time and ending with those that have been in the waiting room the longest period of time." *(ICR, page 18)*

CDC response: To clarify the method for choosing participants, we have modified this section to read:

"The interviewer will choose patients based on the wait time before their appointment, beginning with those with the longest time period between their check-in time and appointment time. This strategy was chosen to limit the amount of extra time a patient would be at the clinic beyond the normal duration of their wait time and appointment." *(ICR, page 18)*

15. OMB comment: Suggested to give/offer HIV informational materials to participants, even if not specifically requested. *(ICR, page 20)*

CDC response: We deleted the phrase "as requested" from the end of the sentence. *(ICR, page 20)*

16. OMB comment: How will you analyze/address potential non-response bias? *(ICR, page 20)*

CDC response: The following was added to the ICR to address this question:

*"*Although the proportion of individuals who accept and refuse participation in the study among those who are approached will be monitored, no additional data beyond the reason for refusal will be collected from those individuals who refuse to participate. Therefore, differences between respondents and nonrespondents cannot be determined.*" (ICR, page 20)*

17. OMB comment: During the conference call between CDC and OMB that occurred on 10/27/09, it was requested by OMB that rather than offering participants $20 to "compensate them for their time," the $20 should be offered as a "token of appreciation."

CDC response: Below is an excerpt from the CDC guidance for developing consent forms:

"It is acceptable in CDC consent forms to describe incentives for participation as compensation for participants' time, trouble or inconvenience, discomfort, and out-of-pocket expenses for being in the study. It is not acceptable to describe payment so it may read as the purchase of a person's participation in research, which may be viewed as coercion."

In light of this guidance, we have *not* inserted the phrase "token of appreciation" as originally requested. We do not believe that the use of a $20 incentive in anyway suggests the purchase of the respondent's participation in this research.