Multi-Site HIV Testing in Mental Health Settings
0920-08BL

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A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention requests approval for a new data collection called 'Multi-Site HIV Testing in Community Mental Health Settings' for a period of two years. Mental health care settings are frequently overlooked for HIV testing and for promoting prevention efforts against the transmission of HIV.[1, 5, 10] Risk behaviors, willingness to be tested, and prevalence of HIV among persons with severe mental illness receiving services across different types of mental health settings have not been well-characterized. In addition, the relationship between risk behaviors, mental illness, and adherence to medical and mental health care are poorly understood.

Through a Cooperative Agreement with CDC, the University of Pennsylvania will implement HIV testing programs in six mental health settings located in Philadelphia and Baltimore. In each city, testing and linkage to treatment services will be offered to individuals receiving mental health services in a general medical hospital psychiatry inpatient unit; a community-based outpatient mental health clinic; and a community-based mental health outreach program.

This project addresses the "Healthy People 2010" priority area of identifying new HIV infections and is in alignment with CDC/CCID/NCHHSTP performance goals to strengthen the capacity nationwide to monitor the epidemic, develop and implement effective HIV prevention interventions, and evaluate prevention programs. In addition, this program addresses the NCHHSTP Division of HIV/AIDS Prevention's priority in developing new methods for diagnosing HIV infection.

Background

People with severe mental illness (SMI), including those with substance use disorders, are at increased risk of infection with HIV compared with the general population.[1-6] Despite the significant risk for co-morbidity, persons with SMI are often not included when planning and implementing HIV programs and interventions by health agencies.[1, 3-5] In addition, there has been insufficient research on the co-morbidity of HIV with mental illness, and the epidemiology of HIV among persons with SMI.[6, 7] Mental illness can also adversely affect individuals' ability to assess the transmission risk for infection. Persons with SMI report high rates of risk behaviors for HIV, including having sex with multiple partners, having sex with partners they know little about, having unprotected sex, and being coerced into unsolicited sexual encounters thus increasing the chances that HIV will be spread.[8, 9] Mental illness can also adversely impact linkage to care and adherence to medical treatment for those who are diagnosed.

In September 2006, CDC published the "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings", which recommend that HIV screening be offered to patients in all health-care settings and that persons at high risk for HIV infection be screened for HIV at least annually. The current project will evaluate the processes and outcomes of implementing HIV testing in a range of community mental health settings. It is anticipated that the project will reveal structural and patient-related barriers to offering testing in

these settings and elucidate effective and innovative approaches to overcoming these barriers. Collection of client-level data on HIV risk behaviors and psychiatric symptoms will provide important insights into the epidemiology of HIV among persons with SMI and the relationship between HIV risk behaviors and psychiatric illness.

Legislative authorities for this data collection are included in Attachment 1. Collection of HIV and AIDS case data is regulated by Title III – General Powers and Duties of Public Health Service, Section 301 (241.)a.

Privacy Impact Assessment

Overview of the Data Collection System

Approximately 1200 clients will be enrolled over two years, with participants completing a brief survey which includes data on demographics, HIV risk behaviors for infection, previous HIV testing and mental health symptoms. Teams of trained HIV counseling and testing staff will offer counseling and rapid HIV testing at implementation sites. Pre- and post-test counseling will adhere to current CDC guidelines for personalized risk reduction counseling and will be completed by trained, experienced research staff. 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. This information will be collected to assess whether or not persons who receive RHT have greater mental health service utilization during the observation period. . Data will be stored for 7 years following completion of the study. 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.

Items of Information to be Collected

Patients will be asked to provide information on demographics, HIV risk behaviors, previous HIV, STI and Hepatitis C testing and mental health symptoms. Demographic and testing history questions are from the National HIV Behavioral Surveillance System Study questionnaire (OMB 0920-0990, expiration date: 3/31/2011). Data collected will help inform the development of testing and prevention programs for HIV in settings which serve persons with SMI.

This project will obtain consent and collect data through face-to-face structured interviews to which includes data on demographics, HIV risk behaviors, mental health symptoms, and HIV, STI and Hepatitis C testing history (Attachments 3a-c) from all participants in the six implementation sites. This is a one-time data collection activity and each potential respondent will be approached and interviewed once during the data collection period. Interview data will be collected electronically by trained interviewers using laptop computers that utilize a secure web-based personal interviewing system. Study participants will not have access to the web-based data collection instrument. Additionally, the web-based system is security protected, preventing unauthorized persons from viewing the data collection system.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

There are no specific websites utilized by this project and no website content directed at children under 13 years of age.

2. Purpose and Use of Information Collection

This project will provide information on the characteristics of persons at mental health clinics who agree to be tested for HIV and, those who are diagnosed with HIV. This study will also collect information about clients' barriers to accessing testing services in the past. This information will be used to inform CDC on the components essential for HIV surveillance to mental health institutions.

Data on client characteristics and risk behaviors will be used to document the need for HIV testing and services in mental health settings and for informing guidance to community mental health settings on incorporating these testing services into the care they routinely offer to individuals with mental illnesses. .

Client characteristics and linkage to care among those clients who are infected will also be used to inform recommendations to address unmet need and strategies to link infected persons to care in mental health settings. 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.

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.

Data from this project are expected to fill a gap in existing data by providing information on persons who have severe mental illness and assisting in planning for providing HIV testing and services to persons with severe mental illness. As this project will provide information that is useful for health care planning purposes, it will be imperative to notify the project areas and stakeholders of the findings of this project as soon as they are available. These data will be distributed to providers, researchers, policy makers and other interested parties through presentations at local, national and international conferences, publications in peer reviewed journals, and presentations at different forums such as, continuing medical education courses and seminars.

Participants and community members will be informed of this project's findings through multiple information conduits. Results will be released on the CDC website, publications in peer-reviewed journals, and presentations at conferences. Local data results will be reported back to the community through means such as local publications, epidemiologic profile reports, presentations to local HIV service organizations and community planning bodies, and at

conferences and workshops. All presentations and publications of the data will include a discussion of the content of the structured interview and the limitations of the study.

Privacy Impact Assessment

Although the identities of respondents are known to local health care providers in Baltimore and Philadelphia and to the interviewers, no identifiers will be transmitted to the CDC. All identifiers will be maintained at the local level as required for public health follow-up purposes.

3. Use of Improved Information Technology and Burden Reduction

Interview data will be collected on laptops utilizing a secure web-based personal interviewing system. This system has already been utilized by the partner agency, the University of Pennsylvania, in similar previous research projects. The research partners at the University of Pennsylvania are licensed to use the software and have extensive experience with implementing interview projects using this electronic data collection system in the field.

The data will be automatically uploaded via a secure wireless internet connection as the research assistant completes each interview and no data will be stored on the laptops. When not able to use the laptops because of possible technical failure, the data will be collected using paper forms, identified with the study identification number for the participant. These data from the paper forms will then be entered into the web-based system once the research assistants can again access the web-based system. All research assistants utilizing this electronic data system will be trained prior to being awarded this privilege. The research team has contracted with the Data Management Unit (DMU) at the University of Pennsylvania to develop and implement this system of data collection, monitoring, and protection.

Experience with using this data collection approach has shown overall reduction in the duration of the interviews; a decrease in the average number of interviewer errors per interview including errors due to incorrect skip patterns, out of range answers, and missing responses; and the elimination of the need for data cleaning associated with data entry and the errors listed above. This reduced burden has also resulted in a reduction in the time between the last interview and the production of a final analysis dataset.

Additionally, the cost of data collection using this approach instead of paper data collection forms is also reduced despite the increased startup costs associated with use of computers and software. The incremental cost of each collected survey decreases with each subsequent interview conducted, so that when collecting several hundred interviews, it is less expensive to use the web-based system than paper. All client interviews will be conducted by trained project staff. This project's survey interview will be administered face-to-face using the web-based approach described above. Paper forms will only be used in the event of equipment malfunction.

Investigators from the project will regularly train the interviewers and convene lessons learned meetings to understand the problems that can occur with the web-based software that is used for conducting the interviews. Automated edit checks and skip patters will be built into the interview program used to collect the data, as a further quality control measure. Use of

electronic data collection will help to reduce the burden on clients enrolled in this project and on implementation sites. Transfer of data collected electronically will eliminate the need for data entry of interview responses at the sites.

4. Efforts to Identify Duplication and Use of Similar Information

A review of currently funded federal programs did not identify potential areas of duplication. No known department or agency programs have evaluated the feasibility of integrating HIV testing and services across the three different types of mental health care settings as proposed in this project. Risk behaviors, prevalence of infections, and willingness to be tested among persons with severe mental illness across these different types of mental health settings have not been well-characterized. In addition, the relationship between HIV infections and mental health symptoms, risk behaviors, and adherence to mental health and medical care are not well understood. Additional data are needed on the characteristics and needs of persons with severe mental illness across these different settings with regard to HIV testing and services, as confirmed by systematic review of the literature and discussions with other federal and non-federal experts.

5. Impact on Small Businesses or Other Small Entities

The 6 mental health facilities are publicly funded and CDC expects that the impact on these mental health facilities will be minimal.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection activity and each potential respondent will be approached and interviewed once during the 2008-2011 data collection period. Persons will be asked if they have been interviewed previously for the survey; those who indicate that they have been interviewed already will not be interviewed again. Each month during the 2008-2011 time period, a sample of clients from the six mental health sites will be selected to participate in the project. The recruitment strategy for this project specifies that data must be collected systematically. Eligible persons will be identified prospectively and interviewed as they are identified at clinical sites.

There are no legal obstacles to reduce the burden.

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

This request fully complies with the guidelines of 5 CFR 1320.5.

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

A 60-day notice to solicit public comments was published in the *Federal Register*, August 1, 2007, Volume 72, Number 147, pp. 42097-42098 (Attachment 2a). A copy of the *Federal Register* notice has been submitted together with this supporting statement. There was one public comment received from the AIDS Institute in Washington, DC, expressing support for the

project and for efforts to improve access to testing and services in mental health settings (Attachment 2b).
Discussions were conducted in 2007 with scientists and public health practitioners from CDC, other federal agencies (including the National Institute of Mental Health and the Substance Abuse and Mental Health Services Administration), and non-federal agencies. All names, affiliations, and contact information are included in Attachment 4. In September 2007, CDC began to hold regular conversations with a team of mental health researchers from the University of Pennsylvania and the University of Maryland, including Drs Michael Blank and Lisa Dixon.

9. Explanation of any Payment or Gift to Respondents

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.

10. Assurance of Confidentiality Provided to Respondents

Although personally identifiable information such as name, address, telephone number will not be collected by the local implementors, participants will be known to the staff who will be conducting the interviews. Hence, this project needs to comply to the Privacy Act. The SORN

for this project was published in the Federal Register volume 57 (252)[Notices] pages 62812 and 62813;on December 31, 1992.

IRB Approval

The protocol approved by the CDC's Institutional Review Board (IRB) and the approval letter are in Attachment 5a and 5b respectively. The protocol approved by the IRB of the University of Pennsylvania is in Attachment 6a. Local IRB review will be sought in all project areas as they are recruited.

Privacy Impact Assessment

A. Respondents' identifying information will not be submitted to CDC for inclusion in the final project dataset.

B. Research and investigations generally. Information collected by CDC under Section 306 of the Public Health Service Act (42 U.S.C. 242k) as part of the HIV/AIDS case data that would permit direct or indirect identification of any individual or institution on whom a record is maintained, and any identifiable information collected during the course of an investigation on either persons supplying the information or persons described in it, is collected with a guarantee that it will be held in confidence, will be used only for the purposes stated in this Assurance, and will not otherwise be disclosed or released without the consent of the individual or institution in accordance with Section 308 (d) of the Public Health Service Act (42 U.S.C. 242m(d)). This protection lasts forever, even after death.

The existing 308(d) confidentiality assurance for HIV/AIDS surveillance data and related projects currently in effect covers this project and will provide stringent confidentiality protection for the data at CDC, but that protection will not apply to data at the cooperative agreement sites. Therefore, a Certificate of Confidentiality pursuant to Section 301(d) of the Public Health Services Act (42 U.S.C. Section §241(d)) is needed to protect the data at the cooperative agreement sites. The application for a Certificate for this project is in the process of being reviewed. A Certificate can be used by the cooperative agreement sites to avoid compelled "involuntary disclosure" (e.g., subpoenas) of identifying information about a participant. It does not prevent voluntary disclosures such as limited disclosure to protect the participant or others from serious harm, as in cases of child abuse (the cooperative agreement sites may not rely on a Certificate to withhold data if the participant consents to the disclosure). The Certificate covers the collection of sensitive information for a defined time period (the term of the project); however, personally identifiable information obtained about participants enrolled while the Certificate is in effect is protected in perpetuity.

Because respondent identities are known to the local sites that will collaborate with CDC on this data collection, project data will be covered by the appropriate CDC Assurance of Confidentiality ("Surveillance of Acquired Immunodeficiency Syndrome (AIDS) and Infection with Human Immunodeficiency Virus (HIV) and Surveillance-Related Data," RK-2001-036, Attachment 6). This Assurance provides the highest level of legal confidentiality protections to the individual persons who are the subject of this data collection, and to the individuals and organizations responsible for data collection. The terms of the Assurance of Confidentiality

reflect the collective experience of CDC, health departments, and the Council of State and Territorial Epidemiologists with respect to the collection, electronic transmission, and dissemination of HIV/AIDS surveillance data. The Assurance includes established policies and procedures governing all aspects of data collection and de-identification, physical security for paper forms and records, electronic data storage and transmission, and the release of aggregate data in forms that cannot be linked back to individual respondents. The protections afforded by the Assurance of Confidentiality last forever, and endure even after the respondent's death.

After project data are collected, local implementors will delete client and physician names and other identifiers from the records transmitted to CDC (see Attachment 3a-c for data collection form). The records maintained by CDC are identified only by a state/city assigned project identification number, and the respondent's date of birth. CDC does not have access to information that would allow CDC personnel to re-link the data to respondent identifiers.

Security of the web-based data entry system which will be utilized is maintained through the use of a double authentication system operated by the DMU at the University of Pennsylvania. Each system user is assigned two username/password combinations. The first username/password combination is one selected by the registered user and provides access to the main DMU web site. The second username and password is assigned by the DMU, and provides access to the data entry portion of the web site. Strict standards are enforced when providing access to the data entry system. Users are assigned only to designated studies within the web entry system, and only the local study PI can authorize this assignment. The local study PI will validate users in writing for access and security assignment. Additionally, all users of the web data entry system must complete the DMU's training and certification. User names and passwords are only assigned to persons who've received the DMU training and certification. The DMU strives to ensure that the entry system is fully operational at all times. System failure procedures require that interviewers have paper copies of all instruments that are administered at every interview. Any user caught sharing his/her login information will have their supervisors alerted, and their accounts closed. If a password is considered comprised, the DMU will be contacted, and a new password assigned.

Encryption security for all project data must meet the current National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS), which meet or exceed Advanced Encryption Standards (AES). See the document "Technical Guidance for HIV/AIDS Surveillance Programs, Volume III: Security and Confidentiality Guidelines" for further information (www.cdc.gov/hiv/surveillance.htm). The data files for this project must be uploaded to the project area's secure storage drive at the completion of each interview. All data files must be transmitted to CDC using the Secure Data Network (SDN).

Although the primary mode of data collection is electronic, paper forms may be used by CDC's collaborators in the event of an equipment failure. If used, paper forms will be filed by the unique project identification number and date of interview, and stored under lock and key at the research offices in Philadelphia or Baltimore. When information is collected using paper forms, the research assistants will be responsible for electronic data entry once the secure web-based data entry system is available. Any paper records that support data collection will be filed by the unique project respondent identification code and the date of visit (not the respondent's name or

medical record number), and stored under lock and key. Respondents will be informed that their data will be maintained in a secured system, that the data will only be used for stated research purposes, and that the data will not be disclosed or released without their consent.

The Assurance of Confidentiality (Attachment 6) is enforced with appropriate training and contractual agreements which clarify the responsibilities of all participants in HIV/AIDS surveillance activities who have access to directly identifiable data or to data that are potentially identifiable through indirect means. State and local health department personnel who conduct HIV/AIDS surveillance are subject to the confidentiality obligations described in the CDC guidelines for the security and confidentiality of HIV/AIDS Reporting System (HARS) data (http://www.cdc.gov/hiv/topics/surveillance /resources/guidelines/guidance/attachment_f.htm) and are required to undergo security and confidentiality training. Project interviewers and data managers will undergo the same security and confidentiality training as required for health department staff. CDC's Procurement and Grants Office will require the inclusion of 308(d) clauses in any HIV/AIDS support services work done by contractors (e.g., data analysis, computer programming, LAN support). All CDC permanent employees and their contractors will be required to attend annual confidentiality training, to sign a nondisclosure agreement and to update their confidentiality agreements on an annual basis. Contractors must sign a "Contractor's Pledge of Confidentiality." Access to HIV/AIDS surveillance data maintained at CDC is restricted to authorized personnel who have signed the "Agreement to Abide by Restrictions on Release of Data" (Attachment 7). CDC-funded cooperative agreements to state and local health departments reference the Assurance of Confidentiality as a condition of award.

C. The informed consent process for respondents will be fulfilled by obtaining a consent document signed by the respondent, or by having the interviewer sign a consent document attesting to the respondent's verbal consent. Model informed consent documents are included as Attachment 8. All sites must obtain consent from respondents and store the consent forms in a secure location, separately from the data collection instruments. Interviewers receive extensive instruction about the importance of safeguarding respondent identity, and procedures to avoid breaching confidentiality.

D. During the consent process, respondents will be informed that they may choose to not answer any of the questions that they are being asked as part of the interview.

11. Justification for Sensitive Questions

A key objective of this project is to describe characteristics of clients in mental health settings who agree to HIV testing, including such factors as mental health symptoms, substance use history, and risk behaviors. 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.

To address these key objectives for this project, it is necessary to ask a specific question about mental health symptoms, HIV risk behaviors, sexual history, and injection drug use. It will also be necessary to ask about these questions to identify the mode of exposure reported by project participants. Identification of the mode of exposure to infection will allow comparison of the study population with others diagnosed with similar infections. Although the information requested is highly sensitive, the purposes of this project cannot be accomplished without their collection. Other questions that may be sensitive to a portion of the respondents include those relating to race, ethnicity, educational level, and identification as transgender. All interviews will be conducted by trained project staff in a private location at the mental health sites where the project is implemented.

12. Estimates of Annualized Burden Hours and Costs

The goal is to interview a sample of 600 persons annually for two years; 300 in each of the two project areas of Baltimore and Philadelphia. 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. Based on the University of Pennsylvania's prior experience working in mental health settings, it is estimated that the client response rate will be 90%. Of the 644 persons approached who agree to be surveyed, it is estimated that 95% of persons will meet the eligibility criteria and 98% will be able to provide informed consent, as determined by the consent comprehension test. Therefore, the goal will be to approach 716 persons annually for participation in the study. The structured interview will take approximately 20 minutes to complete.

Exhibit 12.A: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden hours
Approached client	Eligibility Screener	644	1	1/60	11
Eligible participant	Consent Questionnaire	612	1	10/60	102
Consented participant	Structured Interview	600	1	20/60	200
TOTAL					313

Exhibit 12.B: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total burden (in hours)	Average Hourly Wage Rate	Total Annual Respondent Cost
Approached client	Eligibility Screener	11	$17.75	$195
Eligible	Consent	102	$17.75	$1811

participant	Questionnaire			
Consented participant	Structured Interview	200	$17.75	$3550
TOTAL		313		**$ 5556**

In order to estimate the cost to the respondents, we used the seasonally adjusted average hourly wage earnings of total production and non-supervisory workers on private non-farm payrolls proposed for January 2008 by the US Department of Labor. For each year, the proposed data collection is estimated to cost $5556 for all respondents listed in Exhibit 12.B

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

There are no other costs to respondents associated with this proposed collection of information.

14. Annualized Cost to the Government

Exhibit 14.A. Estimated Annualized Costs to the Government

Expense Type	Government Related Expenses	Annual Costs (dollars)
Direct cost to the Federal Government		
	CDC Medical Officer (Supervisor) (GS-14, .05 FTE)	$5,391
	CDC Project Officer (GS-12, .25 FTE)	$16,923
	CDC Medical Officer (GS-14, .05 FTE)	$5,391
	Travel	$5,000
	Subtotal, direct costs to the government	$32,705
Cooperative Agreement with University of Pennsylvania		$321,293
TOTAL		**$353,998**

Travel is related to providing technical assistance and conducting site visits. Examples of meetings that will be held include interviewer training and investigators' meeting for partners from non-federal agencies.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The following is a brief overview of this project's timeline.

Exhibit 16.A

Activities	Time Schedule
Begin Patient Interviews	1 month after OMB approval
Preliminary Evaluation	12 months after OMB approval
Data consolidation and processing start	24 months after OMB approval

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

The OMB expiration date will be displayed electronically on laptops as a part of the survey software.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified.

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B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Method

The sampling frame for persons selected to participate in this project will be clients at one of the six participating implementation sites. The six mental health settings will be located in Philadelphia and Baltimore, through a cooperative agreement with the University of Pennsylvania. In each city, testing and linkage to treatment services will be offered to individuals receiving mental health services in a general medical hospital psychiatry inpatient unit; a community-based outpatient mental health clinic; and a community-based mental health outreach program.

Eligibility will be determined according to information provided by clients. The population of interest for this project is clients at the selected mental health sites. Eligible persons will be selected prospectively, as described below in the section titled, "Selection of Participants." Through an informed consent process, selected persons will be asked to participate in a structured interview and to provide an oral swab or fingerstick blood specimen for rapid HIV testing.

Respondent eligibility criteria

Eligible persons are those who:

- Are an adult, age 18 or older
- Are able to speak and understand English
- Are willing to receive rapid HIV and other STI testing regardless of known status
- Have the capacity to provide informed consent for participation.

Ineligible persons are those who:

- Do not have the capacity to provide informed consent for participation (including a lack of capacity secondary to active psychiatric symptoms or intoxication).
- Are a prisoner or correctional detainee
- Are unable to speak English

Selection of Participants

An interviewer and counselor/tester will be present in the selected implementation sites and will seek to recruit clients systematically according to the sampling plan for the survey and testing. The overall response rate will be calculated as the percentage of clients approached who agree to participate. The overall response rate, with the $20 incentive, is expected to be 90%.

In the in-patient setting, the interviewer will obtain a roster of new admissions since the interviewer was last at the facility. Providers will be given the opportunity to recommend exclusion of any potential participant whom they feel is medically or psychologically unstable and unable to participate. From the remaining patients on the roster, staff will approach persons based on the length of time they have been on the unit, starting with those who have been on the unit longest (but not previously approached) and ending with those who have been admitted to the unit most recently.

In community mental health clinics, the interviewer will approach persons who have checked in for their appointment at the facility. As with the in-patient setting, clinic staff may exclude certain

persons from being approached if staff feels the individual is medically or psychologically unstable or unable to participate. 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.

For recruitment in the outreach setting, outreach staff members will approach all clients whom they feel are medically and psychologically stable enough to participate in the study and will offer them HIV testing. Staff will then provide information on which clients would like to receive testing to the project HIV counselor. The mobile van will be able to travel to various locations in each city to accommodate the testing schedule for a given day. Following recruitment, the study personnel will explain the study and review the consent form.

Sample Size

The number of interviews has been set based on the estimated number of clients approached, the time and resources available for this project, and the expected level of precision for the sample. Research staff will attempt to enroll a total of approximately 600 new participants annually and will likely meet or exceed this goal. Because this project is mainly descriptive, power calculations, which are used in sample size determinations for testing specific hypotheses, were not performed. Instead, the level of precision, i.e., the estimated 95% confidence interval (CI) half-width that can be expected, was examined. The expected level of precision for a systematic sample was calculated for all six mental health sites (n = 1200 over the 2-year data collection period). The following table shows the expected level of precision for an estimate from these data, such as, for example, an estimate of the proportion of persons with a given mental health diagnosis who report a given risk behavior. A design effect of 2 was chosen for the calculations because that level of design effect is commonly encountered in similar surveys. The CI half-widths in the table are the maximum that would be expected for estimates for a total sample size of 1200 for the project over the 2-year data collection period. The table shows the level of precision to be expected not only for estimates for the entire population (column 2), but also for subpopulations (e.g. racial/ethnic groups) that comprise 50%, 25%, 15% and 10% of the total population (columns 3, 4, 5, and 6, respectively).

N	CI half-width total population	CI half-width subpopn = 50%	CI half-width subpopn = 25%	CI half-width subpopn = 15%	CI half-width subpopn = 10%
1200	4.00%	5.66%	8.00%	10.33%	12.65%
1400	3.70%	5.24%	7.41%	9.57%	11.71%

Project staff will attempt to recruit these 1200 clients by direct contact at clinical sites. This sample size goal has been established based upon the above precision estimates, the resource limitations of the project, and the estimated number of clients approached in the clinical settings.

2. Procedures for the Collection of Information

Structured Interview

All structured interviews will be conducted by trained project staff, in a location that assures privacy in the mental health care setting. Participation in this project is voluntary; a decision not to

participate will not affect an individual's right to mental health, medical, or other services. Respondents may refuse to answer questions or stop participation at any time without penalty. Informed consent must be obtained as required by CDC's IRB and state/local IRBs in the project areas. Each person approached will be invited to be interviewed and to provide an oral swab specimen or finger stick blood specimen for rapid HIV testing. Persons approached can elect not to participate in the structured interview and still provide a specimen for testing. However, no one who refuses all testing will be asked to participate in the interview.

A brief eligibility questionnaire will be administered to determine if the person is eligible to participate in the study (Attachment 3a). The eligibility questionnaire will take approximately one minute to complete.

If a person is eligible to participate, s/he will be asked to provide informed consent process. Informed consent may be obtained by any of the following methods, as determined by the project areas:

- having the participant read and sign the informed consent form;
- having the interviewer read the form to the participant and asking the participant to sign the form; or
- having the interviewer read the form to the participant and indicating on the form that the participant provided verbal consent.

After reviewing the informed consent form (Attachment 8) with the study personnel, potential participants will be encouraged to ask questions about the consent form and the study. Once all the questions have been answered, study personnel will assess the capacity of the client to provide consent for participation by asking the candidate five questions about the project to check his/her comprehension (Attachment 3b). If any question is explained more than two times and the respondent still does not answer the question correctly, correctly then s/he will be determined to be unable to provide informed consent and so will be ineligible to participate. The consent process will take approximately 10 minutes to complete.

Persons who pass the consent comprehension interview will be administered a standardized, structured interview (Attachment 3c). The structured interview consists of questions designed to collect self-reported demographic characteristics, mental health symptoms, and risk and testing behaviors. The structured interview incorporates validated assessment instruments for psychiatric symptoms, including the Behavior and Symptom Identification Scale-24 (BASIS-24) and the standard multi-purpose short-form generic measure of health status (SF-12). Questions on demographics, risk behaviors, and HIV testing behaviors are modeled on questions from the National HIV Behavioral Surveillance System (NHBS, OMB 0920-0990 exp. 3/31/2011). The interview instrument will be programmed into a secure web-based interview program. The structured interview will be administered face-to-face using the web-based interview via a laptop computer.

The laptops will be password protected and the data on them will be encrypted using software approved by the Department of Health and Human Services. No personal identifiers will be included. Structured interviews will be administered using hard copies of the interview in the event of an equipment malfunction. The hard copies of the interview will not contain personal identifiers, and will be kept in a locked briefcase while being transported to and from interview appointments. The structured interview is expected to take approximately 20 minutes.

Participants will receive HIV prevention materials at the end of the interview, referrals to local HIV prevention and care services, and also prevention information from project staff.,

Quality control/assurance

For quality assurance, the field coordinator will observe each interviewer conduct at least three trial interviews, and 1 in 30 actual interviews, and will evaluate administration, accuracy, and completeness. Additionally, interviewers will periodically review each other's administration techniques to ensure consistency across interviewers.

In order to avoid data loss, and to ensure data security, at the completion of each structured interview the data is automatically uploaded via the secure website to the main project database. Once the uploading has occurred, all interview data will be deleted from the laptop computer's hard drive before beginning the next structured interview.

Project staff will regularly train the interviewers and convene "lessons learned" meetings to understand the problems that can occur with the software and hardware that is used for conducting the structured interviews. Automated edit checks will be built into the interview program used to collect the structured interview data, as a further quality control measure.

3. Methods to Maximize Response Rates and Minimize Nonresponse

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. 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.

4. Tests of Procedures or Methods to be Undertaken

The structured interview was developed using validated psychiatric assessment instruments and questions from the National HIV Behavioral Surveillance System, demographics and HIV testing history sections (NHBS, OMB 0920-0990 exp. 3/31/2011). Since these questions comprising the structured interview have been previously validated, tested, and/or used, only internal testing by project staff was needed. Overall pilot testing of the structured interview was done; not more than 9 persons were involved in this testing.

CDC and local project staff will test the skip patterns and responses both electronically and using paper versions of the structured interview. CDC and local project staff will also conduct mock interviews of staff members using the web-based program to interview other project staff.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Drs. Chris Johnson and Patrick Sullivan were consulted about the statistical aspects of the project, including the sampling strategy, sample size, and analytic methods. The following individuals were also consulted:

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Attachment 8
Model Patient Information and Consent Form

February 3, 2021

Study Title: Multi-Site Rapid HIV Testing in Urban Community Mental Health Settings

Investigator Names: Michael Blank, PhD, Seth Himelhoch, MD

You must review this form with a staff member before signing it. If you have any questions, please ask the staff member helping you with this form. Do not sign this form until you are comfortable about being in this study. We will give you a copy of this form to keep.

1. Why are we doing this study?
You are being asked to take part in a research study to help us learn more about offering rapid HIV testing in mental health care clinics and facilities. This study is being conducted by the University of Pennsylvania, the University of Maryland and the Centers for Disease Control and Prevention.

Being in this study is up to you. If you do not want to be in this study, you may stop at any time and for any reason. You may also choose not to answer any questions for any reason. You will not lose any benefits or care which you would get if you were not in this study. It costs you nothing to be in the study. 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.

2. Who can be in this study?
Anyone who is over 18 and who is receiving mental health services.

3. How this study works:
Your participation in the study will take approximately 45 minutes. If you agree to this study, you will be asked to:

(1) Complete a 20 minute survey. We will ask you questions about yourself, about any risks you may have for sexually transmitted diseases and about your mental health symptoms.
(2) Give us an oral fluid specimen or a finger stick blood specimen for rapid HIV testing. Results from your rapid HIV test will be available in 20 minutes. If your rapid HIV test result is reactive, we will take a blood sample to perform a second follow-up test.
(3) Give us permission to review your clinical chart.
(4) Give us permission to review your claims data over the next 6 months, if your insurance is through Medicaid.
(5) Complete a contact information form

4. What are the risks of this study?
There are few risks from this study. You may feel some discomfort from the finger stick. You might feel that some of the questions we ask are personal or embarrassing. You do not need to answer any questions which you don't want to.

5. What are the benefits of the study?
You will receive counseling about ways to prevent HIV and other sexually transmitted infections, and you will learn your own HIV status. If you are HIV-negative, we will talk with you about ways to stay negative. If you are HIV positive, we will help link you into care so that you can receive treatment and stay healthy.

6. Alternatives to participating in this study:
You may choose not to be in this study. Your health care will not be affected. If you choose to not be in the study, you can still receive free HIV testing today.

7. Reimbursement:

It costs you nothing to be in the study. **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.**

8. Confidentiality:
Your answers are confidential. No information about you will be shared with anyone else unless there is a clear danger to yourself or others. Officials who review research to protect people who take part in studies might be provided access to medical or research records which list your name. The HIV test you receive today is a confidential test. This means that your test result will become part of your medical record and will only be shared with the medical staff that takes care of you. If you test positive for HIV, we are required to report this test result along with your name to the city and state health departments. If we need to contact you after today, we will use the contact information you provided on the contact form. Information collected about you will be kept in a locked file which only the study researchers have access to. These files will be destroyed when the study is complete. Any publication or presentation which results from this research will not identify you by name, and any details that could make your identity known will not be included.

9. Voluntary Participation:
Being in this study is up to you. You may stop being in the study at any time. You will still receive care if you choose not to be in this study.

10. Injury/Complications:
If any physical injury results from the research procedures, medical treatment will be provided without cost to you, but compensation is not otherwise available from the research team. If you have any questions or believe that you have been injured in any way by participating in this research project, please contact Dr. Michael Blank at (215) 349-8488.

12. Questions/Problems/Follow-up:
You will be given a copy of this form for your records. If you have any other questions about this study after leaving today, you may also contact Dr. Michael Blank by telephoning (215) 349-8488.

If you would like additional information about your rights as someone taking part in this study, you may contact the Director of Regulatory Affairs for the University of Pennsylvania by telephoning (215) 898-2614

If you have any other questions, concerns, or problems while you are here, please tell the person who interviews you.

By signing below, you are agreeing that:

You have read this form and reviewed it with a staff member;

All of your questions about taking part in this study have been adequately answered by staff; and

You agree to take part in this research study.

Printed Name of Subject

Date & Time

Signature of Subject

Signature of Legally Acceptable Representative, *if applicable*

Date & Time, *if applicable*

Printed Name and Relationship to Subject, *if applicable*

Investigator's Signature

Attachment 9
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February 3, 2021

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Attachment 10
Consent for release of confidential medical information

February 3, 2021

Consent for release of confidential medical information

Name of Institution

AUTHORIZATION AND CONSENT FOR RELEASE OF CONFIDENTIAL MEDICAL RECORDS

I hereby authorize [physician's office, clinic or hospital, address, telephone] to furnish my complete health record, and if my insurance is through Medicaid, my claims data, to the [name of site, address, telephone] for visits occurring from _____ through _____. The purpose of which will be documenting health care visits and laboratory data for a research study, "Multi-Site Rapid HIV Testing in Urban Community Mental Health Settings." Researchers will use this information to describe use of medical services after HIV testing.

. The person named below is participating in this study.

Note: These records may contain information relating to Acquired Immunodeficiency Syndrome (AIDS), and Human Immunodeficiency Virus (HIV). These records may also contain evidence of treatment for alcohol or drug use, or treatment for a psychiatric condition. I understand this information is protected by law under certain conditions. By signing this statement, I am authorizing release of this information to the requesting party above.

Unless otherwise revoked, this authorization will expire eighteen months from this date _____ 20__. The above information will not be given, sold, transferred or in any way related to any other person not specified in the consent form without first obtaining my additional written consent. I understand that I have the right to revoke my authorization at any time; that if I wish to revoke this authorization I must do so in writing; and that I must present the written revocation to the records management department of [physician's office, clinic or hospital]. I further understand that the revocation will not apply to my insurance company when the law provides my insurer with the right to contest a claim under my policy.

I may choose not to release my health records. I may participate in the research without authorizing release of my health records. If I choose not to release my records, my health care will not be affected. I understand that I may inspect or copy the information to be used or disclosed. I understand that any disclosure of information carries with it the potential for an unauthorized redisclosure, and the information may not be protected by federal confidentiality rules. If I have questions about disclosure of my health information, I can contact:

_____

Privacy Officer for [physician's office, clinic or hospital]

Address	Tel. number
Signature of patient (authorized representative)	Date
Signature of witness	Date