"Evaluation of Pharmacy Syringe Access Linked to HIV Testing for Injection Drug Users in New York City (Pharm-HIV)"
**0920-09AF**

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**Title**

**Table of Contents**

**Attachment 1** Authorizing Legislation
1a. Section 301 of the Public Health Service Act
1b. Section 308(d) of the Public Health Service Act

**Attachment 2** 60 day Federal Register Notice
Federal Register notice.

**Attachment 3** Data Collection Forms

3a. Pharmacy Staff Baseline Survey
3b. Pharmacy Staff Monthly Survey
3c. Syringe Transaction and Referral Log
3d. Pharmacy Staff Six Monthly Survey
3e. Pharmacy Staff Exit Survey
3f. Pharmlink Participant Baseline Survey

**Attachment 4** Informed Consent Forms

4a. Pharmacist Consent
4b. Pharmacy Staff Consent
4c. Syringe-customer participant Referral Consent
4d. Syringe-customer participant In-Pharmacy Testing

**Attachment 5** Telephone Interview Scripts
Pharmacist Telephone Screening and Enrollment Form

**Attachment 6** Institutional Review Board Approvals
6a. IRB Determination – Centers for Disease Control and Prevention
6b. IRB Determination – New York Academy of Medicine

**Supporting Statement**

**Section**
**A. Justification**

**1. Circumstances Making the Collection of Information Necessary**
The Centers for Disease Control and Prevention (CDC) requests approval for a new data collection called "Evaluation of Pharmacy Syringe Access Linked to HIV Testing for Injection Drug Users (IDUs) in New York City (Pharm-HIV)" for 3 years.

This information collection request is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

Background

Injection drug use accounts for 16% of all new HIV cases in the US. Early diagnosis of HIV enables early intervention and thus longer survival and postponement of AIDS defining conditions. For injection-drug users (IDUs), who are at high risk of acquiring HIV infection, HIV testing may not be readily accessible.

HIV testing in the U.S. occurs mainly in medical settings, and many persons at risk for acquisition of HIV do not have economic access to clinics or primary care services. Pharmacies could be excellent venues where HIV prevention could reach many at risk for HIV. There are examples of HIV testing programs at non-traditional settings, such as bathhouses that provide HIV testing services to men who have sex with men. These programs have been successful in reaching a large number of individuals at high risk and have gained acceptance within that community. Since the FDA approval of the new rapid HIV testing methodology, HIV testing in community and non-clinical settings is feasible, especially because the rapid HIV test kits are waived under the Clinical Laboratory Improvement Amendment (CLIA) of 1988 for use in non-clinical settings.

Syringe exchange programs (SEPs) have increased access to sterile injecting equipment and have proven to be effective interventions to injection-related HIV risks. The New York State legislature established The Expanded Syringe Access Demonstration Program (ESAP) in 2001 to reduce HIV transmission among IDU by increasing the sources for sterile syringes in pharmacies. The ESAP program allows for regular contact between pharmacists and their IDU syringe customers, thus paving the way for other pharmacies in New York and other cities, to act as access points to health and social services among IDU customers. The expansion of pharmacy

services to include referrals for IDU syringe customers is based on the successes of SEPs, which provide many services beyond syringe exchange. As a source of sterile syringes, pharmacies are an ideal location to provide HIV testing service referrals to IDUs who do not use SEPs or are not aware of the additional services available at SEPs.

Since 2003, over 2,500 pharmacies have registered with ESAP in New York State. A study found that including pharmacists in HIV prevention efforts, through ESAP, extended the reach of organizations that otherwise would not be able to reach the IDU population. It was also demonstrated that pharmacists are trustworthy and comfortable with their role in HIV prevention. In an August 2004 pharmacy telephone survey in New York City, the New York Academy of Medicine examined opinions about drug treatment and other public health services for IDU syringe purchasing customers. Of the 151 ESAP registered pharmacies surveyed, 87% of pharmacists were willing to take the time to offer drug abuse treatment and other health-related information to their IDU customers. The New Academy of Medicine has access to the list of ESAP registered pharmacies.

This proposed information collection is authorized under Section 301 of the Public Heath Service Act (42 U.S.C. 241) to "… cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies related to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man…". (Attachment 1)

Privacy Impact Assessment

The New York Academy of Medicine's (NYAM) Center for Urban Epidemiologic Studies (CUES) will manage and direct the study. Participants' names and contact information will be kept in a locked file cabinet at the NYAM/CUES project offices, separated from the other project documents. Each participant will have a unique project identification number and all interview forms will include only this identification number. A separate form linking the participant's name with their unique identifier will be in stored in a locked cabinet and accessed in the event a participant has to be contacted by project officers. The personal identifiable information will be destroyed when the participant is no longer needed for the project. CDC will not have access to any personal identifiable information that may be collected by the NYAM/CUES project personnel.

Overview of the data collection system

During the first year the NYAM/CUES will select a sample of 12 ESAP-registered pharmacies that are situated within predefined target neighborhoods in Harlem where there are high levels of injection drug use. Two different types of data will be collected and analyzed in this project: The attitudes of pharmacists and the attitudes of IDU syringe customers of the pharmacies.

Pharmacists and pharmacy technicians: There will be a total of four different data collections among the pharmacists and pharmacy technicians. These are; 1) selection (pharmacists), 2) monthly monitoring(pharmacists),, 3) daily syringe logs (technicians); and 4) semi-annual assessment (pharmacist and technicians). Pharmacy technicians will maintain daily logs of syringe transactions and HIV referrals. NYAM/CUES will use a standardized screening instrument "Pharmacy Telephone Screening and Enrollment Form" (Attachment 5) to select 12 pharmacies within the target neighborhoods that are eligible and willing to participate in this pilot trial.

For the 12 selected pharmacies, the "Pharmacy Staff Baseline Survey" (Attachment 3a) will be administered to two pharmacists and two pharmacy technicians. NYAM/CUES staff will also visit the 12 pharmacies on a monthly basis and administer the "Pharmacy Staff Monthly Survey" (Attachment 3b) to one pharmacist who is available at the time of the visit. Pharmacy technicians will complete the syringe transactions and HIV testing referrals on the "Syringe Transaction and Referral Log" (Attachment 3c). NYAM/CUES staff will collect these logs during their monthly visit to the pharmacies. Every six months "Pharmacy Staff Six Monthly Survey" (Attachment 3d) will be administered to two pharmacists and two pharmacy technicians. During the months that the six monthly surveys are completed, the "Pharmacist Staff Monthly Survey" will not be completed. At the end of the study period, the "Pharmacy Staff Exit Survey" (Attachment 3e) will be administered to two pharmacists and two pharmacy technicians.

IDU syringe customers will provide information one time. IDU syringe customers who are referred for HIV testing will be asked to return to the pharmacy in one month to complete the "Pharmlink Participant Baseline Survey" (Attachment 3f). Each syringe-customer participant who is assigned to be tested for HIV in the pharmacy will be asked to complete the "Pharmlink Participant Baseline Survey" (Attachment 3f) immediately after the HIV test is administered. Syringe-customer participants are informed that they may refuse to answer any question or to drop out of the study at any time they feel uncomfortable with the process.

The investigators at NYAM/CUES will maintain data indefinitely (see section A-10).

Items of Information to be collected
NYAM/CUES will collect name, date of birth, race, ethnicity, and contact information for all IDU participants. Attachments 3d - 3f include the data elements that relate to the pharmacists' and pharmacy technicians' experiences and attitudes regarding syringe exchange and HIV testing at their facility. These data elements include practice patterns of numbers of prescriptions filled, types of counseling provided to customers, times and experience discussing HIV testing with clients, sales of syringes, numbers and characteristics of syringe-customers per month, and perceptions of syringe-customers interest in receiving HIV testing referrals by the pharmacy staff and HIV testing in the pharmacy.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age.
There will be no websites or internet content directed at children under the age of 13.

## 2. Purpose of Use of the Information Collection

This information contributes to CDC's Mission to expand the availability of HIV testing services to hard-to-reach persons throughout the community. This program is funded through the Minority AIDS Research Initiative from the Epidemiology Branch of the Division of HIV/AIDS Prevention of the Centers for Disease Control and Prevention for four years, beginning Oct 1, 2007 and ending September 30, 2011. This project is consistent with the CDC mission to prevent HIV disease. In support of the CDC, the Division of HIV/AIDS Prevention (DHAP) is committed to assist state and local health departments in the preparation, expansion, execution, assessment, and the improvement of HIV prevention programs. Specifically, DHAP's mission statement includes: "… provides leadership in developing research in epidemiology, surveillance, and other scientific aspects of HIV/AIDS prevention,...". The Epidemiology Branch has among its mission statement: "conducts both epidemiologic and behavioral studies to evaluate appropriate biomedical interventions for preventing HIV infection (primary prevention)…."

Currently, there is no available information related to using pharmacies as community HIV testing sites nor the acceptability of HIV test referral for injection drug users who use syringe

exchange programs. The information learned in this program will inform other similar efforts in New York City and in other pharmacies in the United States. Access to pharmacies is simple and a socially unsuspicious act that can potentially overcome obstacles of distance and stigma around HIV testing while taking some of the burden from health departments. Integrating rapid HIV testing protocols into pharmacies will increase access to HIV testing in urban, suburban, and rural settings.

CDC envisions that the findings from this study will expand access to HIV testing and referral services in the community and pharmacies will become HIV testing sites for IDUs. In order to realize this vision CDC anticipates implementing larger feasibility studies to reach persons at risk for HIV through networks of pharmacies that join a response to HIV testing.

The limitations to generalizability of findings from this pilot collection are that the findings are derived from a limited number of participants from a defined geographical location. The lessons learned from this research project will inform CDC in the development of large models for offering HIV testing at pharmacies.

The results of this information collection will be analyzed and reported in scientific publications in peer-reviewed scientific and public-health journals and presented in abstract form at scientific and public-health meetings.

Privacy Impact Assessment Information.

Individually identifiable information (IIF) will be collected by the research staff from NYAM/CUES to conduct the study. It will be used by study staff to contact study participants to remind them about return appointments. Thus, confidential information will be collected and loss of confidentiality could potentially result in harm to the participant. The study has requested a Certificate of Confidentiality from CDC to protect the privacy of research subjects by protecting investigators and institutions from being compelled to release information that could be used to identify subjects with a research project.

No IFF will be available to or shared with the CDC. Analysis of the dataset will take place at the NYAM.

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

The “Pharmacy Staff Baseline Survey” (Attachment 3a), “Pharmacist Staff Monthly Survey” (Attachment 3b), “Pharmacy Staff Six-monthly Survey” (Attachment 3d) and “Pharmacy Staff Exit Survey” (Attachment 3e) will be administered to pharmacy staff by research staff using a computerized survey tool, Questionnaire Development System (QDS) Version 2.5 R004 which is a Computer Assisted Personal Interview (CAPI), so information will be stored as it is collected.

The “Pharmlink Participant Baseline Survey” (Attachment 3f) will be administered to syringe-customer participants using Audio Computer Assisted Self Interview (ACASI) which will be overseen by a trained NYAM/CUES researcher and will last approximately 20 minutes. This software, provided by Questionnaire Data Systems (QDS), asks survey questions via headphones while a participant keys in their answers using a touch screen tablet personal computer. The ACASI system allows the participant to both read and hear each question, and is programmed so that questions must be answered in a consecutive order. Skip patterns are automatic. Participant answers are automatically stored in the ACASI memory. If the participant is unable to access the ACASI system or if there is a technical problem, paper questionnaires will be available as back-up.

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

The NYAM has conducted research and evaluations on ESAP in New York pharmacies since their inception. No ESAP pharmacies are providing HIV testing referrals or HIV testing services in the pharmacy. Thus, there is no similar information available in New York City. This information collection of HIV testing and referrals in pharmacies does not duplicate any other effort. A search of PubMed for published articles regarding HIV testing in pharmacies did not return any manuscripts to this effect.

A search of the National Institutes of Drug Abuse (NIDA) website revealed two projects aimed at increasing HIV testing among drug abusers in drug abuse treatment programs. The first project titled “HIV Rapid Testing and Counseling in Drug Abuse Treatment Programs in the U.S.” (Clinical Trials Identifier Number = NCT00809445) is a randomized controlled clinical trial in which individuals receiving drug abuse treatment will be recruited to participate in a multi-center HIV testing and counseling study. The purpose of this study is to assess the relative effectiveness of three HIV testing strategies on increasing receipt of HIV test results: (1) on-site HIV rapid testing with brief, participant-

tailored prevention counseling, (2) on-site HIV rapid testing with information only, and (3) referral for off-site HIV testing. The study will also assess the effectiveness of the three testing strategies in reducing HIV sexual risk behaviors. Injection drug risk behavior will be a secondary outcome. Participants will complete a baseline assessment to report their demographics, HIV testing history and sexual and drug-using risk behaviors, and will be randomized to one of three groups. At one month post-randomization, participants will complete a follow-up assessment to determine whether or not they received their HIV test results. At six months post-randomization, participants will complete a follow-up assessment to assess any changes in their HIV sexual risk behaviors.

The second trial identified in the NIDA database is “HIV and Hepatitis Care Coordination in Methadone Treatment” (Clinical Trials Identifier Number = NCT00608192). This randomized clinical trial will examine the effectiveness of a strategy of HIV and Hepatitis Care Coordination (HCC) consisting of testing, education, counseling and vaccination for methadone maintenance patients compared with standard Testing, Education, and Counseling (TEC). In the HCC model, HIV and hepatitis screening, and HAV and HBV vaccination will be done on site (methadone maintenance programs) and participants receive on site theory-based HIV and hepatitis education, counseling, and case management to promote adherence to HIV and HCV evaluation; in TEC hepatitis screening is done on site, but vaccination and medical care will be provided by off site referral. Primary aims are to assess the impact of the HCC intervention on adherence to HAV and HBV vaccination and attendance at an initial appointment with an HIV and/or HCV care provider. Secondary aims include examining intervention effects on HIV and hepatitis knowledge, risky behaviors, alcohol use; follow-up with later stages of HIV and hepatitis C care; to identify psychological mediators of intervention outcomes; and to estimate the incremental cost of the HCC intervention to facilitate fuller economic evaluations of the intervention if proven effective.

The proposed trial in this information collection would compliment the NIDA studies with similar goals to improve access to HIV testing for substance abusers, but through pharmacies instead of drug abuse treatment programs. Importantly, active substance abusers (i.e. those coming to pharmacies for clean needles) would often not be in a drug abuse treatment program, thus this proposed study will reach a population of active drug abusers that studies based in substance abuse programs may not reach.

**5. Impact on Small Business or Other Small Entities**

The collection of information may impact independently owned small individual pharmacies selected for this study. The information collection in the pharmacy includes a daily log sheet to track syringe sales to customers (see section 6 Consequences of Collecting the Information Less Frequently). This is a five minute effort by one pharmacy staff member per day and is in keeping with the types of records (sales) that a pharmacy would typically keep.

To ease the burden on the pharmacy staff members, the short monthly interviews and longer baseline, six-monthly and end of study surveys will be administered by research staff using a computerized survey tool, Questionnaire Development System (QDS) Version 2.5 R004 which is a Computer Assisted Personal Interview (CAPI), so information will be stored as it is collected.

The short monthly surveys of one pharmacy staff member at each of 12 pharmacies are estimated to take 10 minutes each. The longer baseline, six-monthly, and at the end of the study surveys for four pharmacy staff members at each of 12 pharmacies are estimated to take 20 minutes each.

**6. Consequences of Collecting the Information less Frequently**

Participating pharmacy staff will complete the following information collection instruments:

- A questionnaire at baseline, semi-annually, and at the end of the study. This is necessary to determine how the knowledge, attitudes, and beliefs of pharmacy staff evolve over time while implementing this novel service. The exit survey will also capture the pharmacists' and technicians' overall experience providing expanded pharmacy services in the study. Collecting this information less frequently would result in less understanding of the overall experience of offering HIV tests in pharmacies.
- Monthly surveys administered by research staff. These will serve as a tool for research staff to inquire about challenges and problems in order to help the pharmacy staff better carry out the study. Collecting this information less frequently would result in less timely improvements to the study conduct.
- A syringe-exchange log daily to track the volume of business regarding syringe exchange so that NYAM/CUES may learn the relative effort needed in order to identify syringe-customers in need of HIV testing and to calculate the ratio of number of persons screened to number of persons tested for HIV. Collecting the information less

frequently would render us unable to estimate this important variable for future program planning.

Syringe-customer participants will complete a single survey only one time.
Summary of the information collection and instruments that will be used in this study are shown in Table 1.

Table 1. Information collection outline

| | |
|---|---|
| Pharmacy enrollment<br>Attachment 5 | Time 0 |
| Pharmacist and Pharmacy Technician baseline survey.<br>Attachment 3a | < 1 month |
| Monthly assessments<br>Attachment 3b | Months 2-5, 7-11, 13-17 |
| Pharmacist and Pharmacy Technician semi-annual survey<br>Attachment 3d | Months 6, 12, 18 |
| Pharmacy Technician Syringe sales and referral log<br>Attachment 3c | Months 1 – 18 |
| Pharmacist and Pharmacy Technician exit survey<br>Attachment 3e | Month 18 |
| Syringe-customer study participant (Pharmlink Participant) Baseline Survey<br>Attachment 3f | Months 2 – 18 (continuous as syringe customers consent). |

There are no legal obstacles to reduce the burden.

**7. Special Circumstances relating to the Guidelines of 5 CFR 1320.5**

The 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 on 11/19/2008(Attachment 2). There were no comments received in response to the 60-day federal register notice.

This protocol was developed collaboratively between the New York Academy of Medicine and the Centers for Disease Control and Prevention. The persons consulted outside of the CDC are:

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

NYAM will provide ESAP Pharmacies with an incentive of up to $1045 for the 18 month period. It is left to the pharmacy's

discretion as to how the amount is dispensed among their staff. This total was arrived at assuming an *incentive* of $25 per 20 minutes for completing the baseline survey, 2 follow-up surveys at 6-months and 12 months, and exit survey completed at 18 months– this totals 4 surveys over 18 months for each of 4 persons in each pharmacy for a total of $400 per pharmacy. It is necessary to have 4 persons (2 pharmacists and 2 pharmacy technicians) complete the surveys in order to collect a diversity of responses as to the feasibility and acceptability of this project of pharmacy staff. It is useful to determine perception of the program differs amongst pharmacy staff in the same environment and compared between other pharmacy stores. Some level of redundancy is acceptable to collect from the 4 pharmacy staff in order to determine if the understanding of the functioning of the pharmacy and how the HIV testing referral or in-store program is consistent among staff.

In addition, an incentive of $25 is allotted for each completed monthly survey – this totals 15 monthly surveys over 18 months for a total of $375 per pharmacy.

NYAM will offer both, one-on-one training in pharmacies and seminar-style training sessions at NYAM for participating pharmacy technicians. NYAM/CUES staff will administer additional trainings as deemed necessary at individual pharmacies in order to reinforce research activities or to train newly-hired staff. One-on-one trainings will include training on the use of log sheets to record syringe sales, engaging IDU syringe-customers, and protocols for inviting IDU syringe-customers to participate in the IDU survey component of the study. The pharmacy staff will also undergo at least one training seminar at NYAM/CUES offices to 1) familiarize pharmacy staff with the characteristics, needs, and HIV risk of the local IDU population, 2) present strategies for engaging customers in conversations and for creating a comfortable and non-judgmental environment, and 3) provide pharmacy staff information about HIV services and contacts at a variety of service organizations in Harlem. In addition, pharmacy staff from the two pharmacies offering HIV testing will be trained to provide information on their pharmacy’s on-site HIV testing and counseling services.

Finally, an *incentive* of $15 per month is provided to the pharmacy to address *the extra burden* associated with completing daily logs of syringe sales. This will total $270 over 18 months.

Overall, incentives are provided to pharmacy staff in this study for completion of vital study tasks that impose exceptional burden on pharmacy staff (e.g., survey completion, daily syringe sale logs) given the time demands in the pharmacy setting. However, if this program demonstrates feasibility and is selected for widespread dissemination, incentives will not be necessary for the pharmacy staff as the tasks providing extra burden in the study will no longer be performed.

Injection-drug-using syringe customers who are in the group referred to HIV testing at another site will be paid an *incentive* of $10 for doing the survey upon return to the pharmacy and an additional *incentive* of $5 if they bring their appointment card with them. Injection-drug-user syringe customers who are in the group where the HIV testing is performed in the pharmacy will be paid an *incentive* of $10 for doing the survey immediately after the HIV testing. Providing incentives to the syringe-customer participants is an effort to *improve coverage of specialized respondents or hard to reach populations*.

There is *equity in the compensation* for the syringe-customer participants in each of the groups. The additional $5 paid to the syringe-customer participants referred to HIV testing is to encourage return of the appointment card so the study team can accurately collect data on the HIV testing site visited. The syringe-customer participants in the group that had HIV testing done in the pharmacy do not have this asked of them.

Syringe-customer participants are not paid to have the HIV test done. Additionally, they can participate in the survey and receive the incentive even if they have not had the HIV test done.

**10. Assurance of Confidentiality Provided to Respondents**

The protocol #5425, titled "Evaluation of Pharmacy Syringe Access Linked to HIV Testing for Injection Drug Users in New York City (Pharm-HIV)", has been received a non-research determination as CDC has been deemed to be “not engaged” directly in research in this protocol by the National Center for National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (NCHSTP) and therefore is no longer subject to CDC IRB (Attachment 6a) requiring only local IRB approval. The CDC has terminated the CDC IRB protocol for this study. The protocol has also been approved by IRB for The New York Academy of Medicine for one year– December 4, 2008 – December 3, 2009 and renewed in 2009 October 13, 2009 – October 12, 2010 (Attachment 6b).

All efforts will be made to ensure that the participants are assured that the information they provide will be available only to the interviewer and the project research staff. The survey in the pharmacies will be conducted in a private room or semi-private consulting area previously identified by NYAM/CUES research staff. Measures will be taken to ensure confidentiality even if private space is unavailable. To accommodate this possibility, tablet personal computers will be outfitted with privacy filters which prevent individuals sitting on either side of a study participant from seeing what the participant is reading on the tablet screen. If there is not a wall behind the participant while they are taking the survey in the pharmacy, a NYAM/CUES research staff person will stand behind them to block the remaining field of vision for the information on screen. The research staff member standing behind the participant will not look at the screen while the participant is taking the survey and will assure the participant that this is the case. Their only purpose in standing behind the participant is to block the remaining field in which the survey might be visible to other individuals in the pharmacy.

Quantitative data will be collected from each participant through the HIV testing questionnaire. NYAM/CUES will assess several different variables including basic demographic information, injection behavior, HIV testing knowledge, attitudes, information received about or usage of drug treatment and/or other services, and other HIV risk behaviors. All information will remain confidential and illicit behaviors will be covered under the Federal Certificate of Confidentiality. All answers that are collected will be kept private to the maximum extent permitted by law: Section 301(d) of the Public Health Service act [42 U.S.C. 241 (d).]

**Privacy Impact Assessment Information**

The Privacy Act is not applicable to this request. Personal identifiable information is collected by and used to meet the project needs by a limited number of project personnel. After the person has contributed all the information needed for the project there will be no further contact with the person. This list of persons will not be included in the data collection forms used for this project and will never be linked to the main project data bases.

NYAM/CUES will collect date of birth, gender, race, and ethnicity of participants but this information will not be transmitted to

nor accessed by CDC. Identifiable information will not be filed or retrieved by the name of the individual by CDC or NYAM/CUES.

The data collected will be stored in a computerized database with password access limited to project staff. Each participant will be assigned a unique identifying number which is the only identification visible in the databases. The participant identification number in the NYAM/CUES database will be unlinked from personal identifiers at the end of the project. The NYAM/CUES number will be used for each record in the database; no contact or personal information will be linked to the records. All analyses will use aggregated data such that no individual can be identified from summary table cells.

Participants' names and contact information will be kept in a separate locked file cabinet at the NYAM/CUES office. There will be a separate form that links the participant's name with their unique identifier in case a participant is ever needed to be contacted about information or results from the study. This form will be stored on a separate computer, password-protected and only accessible to the NYAM's principal investigator and project director. Participants' names and the link to the unique identifier will be destroyed at the end of the study period.

The categories used for race/ethnicity are organized into the OMB approved racial categories of American Indian or Alaskan Native, Asian or Pacific Islander, Black or African-American, Native Hawaiian or other Pacific Islander and White and the ethnic category of Hispanic or Latino and not Hispanic or Latino.

The study has requested a Certificate of Confidentiality from the Centers for Disease Control and Prevention to protect the privacy of research subjects by protecting investigators and institutions from being compelled to release information that could be used to identify subjects with a research project.

Syringe-customer participant data will be collected via Audio Computer Assisted Self Interview (ACASI). This software, provided by Questionnaire Data Systems (QDS), asks survey questions via headphones while a participant keys in their answers using a touch screen tablet PC. NYAM/CUES research staff will instruct the participant on how to complete the survey using ACASI. The ACASI system allows the participant to both read and hear each question, and is programmed so that questions must be answered in consecutive order. Skip patterns are automatic. Participant answers are automatically stored in the ACASI memory. If the participant is unable to access the ACASI system or if

there is a technical problem, back-up paper questionnaires will be available. The surveys will be conducted in a private room or semi-private consulting area previously identified by NYAM/CUES research staff. Measures will be taken to ensure privacy even if private space is unavailable. To accommodate this possibility, tablet PCs will be outfitted with privacy filters, which prevent individuals sitting on either side of a study participant from seeing what the participant is reading on the tablet screen. When using a privacy filter, only individuals directly facing the tablet screen are able to read the information on it. If there is not a wall behind an syringe-customer participant while they are taking the survey in the pharmacy, a NYAM/CUES research staff person will stand behind them to block the remaining field of vision for the information on- screen. The research staff member standing behind the participant will not, however, look at the screen while the participant is taking the survey, and will assure the participant that this is the case. Their only purpose in standing behind the participant is to block the remaining field in which the survey might be visible to other individuals in the pharmacy.

Quantitative data will be collected from each participant through the HIV testing questionnaire. NYAM/CUES will assess several different variables including basic demographic information, injection behavior, HIV testing knowledge, attitudes, and behavior, information received about or usage of drug treatment and/or other services, and other HIV risk behaviors such as sexual practices. All information will remain confidential and illicit behaviors will be covered under the Federal Certificate of Confidentiality.

Measures will be taken to ensure the security of participants' data once the survey has been completed. After every interview, NYAM/CUES research staff will back-up data onto a password-protected USB drive and at the end of the day, NYAM/CUES research staff will check the files they have collected against the IDU Survey log sheet to ensure that files are present and password protected for all participants interviewed. As a benefit of the QDS software, data collected is automatically encrypted, password protected, and can only be modified or viewed by designated data warehouse managers with the password and specific software which will not be on the tablet personal computers brought to pharmacies. Warehouse manager software will only be on the project director's computer at NYAM. Thus, even if a tablet or USB drive is lost or stolen, data will not be accessible or readable on those devices and no identifying information or names will be stored on those devices. Upon returning to NYAM, the USB

drive will be given to the project director who will create an ACASI data log of that day's surveys in the warehouse manager on the project director's desktop PC. A research staff member will compare raw data files to the ACASI data logs to ensure all data has been transferred. Once verification has taken place the project director will delete the records from the tablet and USB drive. All files will be date and time stamped for verification of file being opened, received and password protected. The files will be labeled by site number and date. A checklist of ACASI and data transfer related activities will be completed for each site.

All information collected from pharmacy staff will be password protected and, in the case of the monthly surveys which will be administered in pharmacies using a laptop computer, immediately saved to a flash drive which will also be password protected. Personal identifying information about pharmacists and pharmacy technicians will be kept in a separate locked file cabinet and will not be entered in any database. There will be a separate form which will link the pharmacist/ pharmacy technician name with their unique identifier which will be stored on a separate computer, password-protected and only accessible to the principal investigator and project director.

The data collected for the monthly surveys will be stored in a password-protected computerized database for the monthly surveys via the CAPI software. Log sheets will be scanned and image files and databases will be password protected. Participating pharmacies will be assigned a unique identifying number, which will be used on log sheets, and individuals will be assigned unique identifying numbers which will be used on surveys. These numbers will be used for each record in the database; no contact or personal information will be linked to the records in the database. Demographic data will be compiled in grouped categories only, such that no individual will be able to be identified retrospectively.

Only observational data will be collected during outreach activities to pharmacies, injection drug users and community based organizations. Data are collected primarily for quality control reasons. Pharmacies visited during outreach will be assigned a unique identifying number, which will be used on log sheets used to track pharmacy visits by research staff. These numbers will be used for records in a database. Any identifying information about pharmacies visited during outreach will be kept in a separate locked file cabinet and will not be entered in any database, and no personal or contact information from pharmacy

staff will be collected during outreach. This data serves to update NYAM's records of ESAP registered pharmacies and enable quality control of outreach activities. The outreach is intended to promote ESAP knowledge and participation at pharmacies. Likewise, no personal identifying information will be collected during IDU street outreach. IDU outreach is intended to encourage IDU patronage of pharmacies in Harlem, especially pharmacies participating in this study.

Participating pharmacy staff members voluntarily join the study and are advised that they may withdraw at any time with no adverse repercussions. Pharmacy staff will also be advised that only CDC project staff will have access to the information from the project and that reports generated for distribution will be based on aggregated data. Pharmacy staff members do not provide information personal behaviors.

Syringe-customer participants are also counseled regarding the voluntary nature of their participation. NYAM/CUES project staff will ensure that the syringe-customers understand that they may withdraw from the study at any time. Syringe-customer participants will also be assured that the pharmacy staff will not be informed whether or not they participate in the NYAM/CUES project. Syringe-customers are also assured that they may leave the study at any time.

**11. Justification for Sensitive Questions**

The study asks syringe-customer participants questions of a sensitive nature. Persons who are active injection-drug users will be asked to describe and quantify their drug use. This information will help CDC determine the extent of drug use. The information collected from this project may allow us to design and target interventions for persons with certain injection-drug use patterns.

Questions pertaining to sexual behavior and attitudes are asked of the syringe-customer participants. These questions are needed to evaluate HIV risk behaviors. Participants will receive risk reduction counseling as a standard part of the study.

Past history of HIV testing is requested to determine if the participant has been tested for HIV in the past and if the test is known to be positive. This information may affect employability or insurability. It is essential to know when the participant was last tested along with the result of that test in order to determine if the person is known to be HIV positive

already.  In addition, if the study can determine that being provided referrals for HIV testing from a pharmacy or if being offered HIV testing in a pharmacy is more appealing to syringe-customer participants, NYAM/CUES can quantify the likelihood of increased HIV testing in comparison to past HIV testing patterns.

Questions pertaining to past history of discrimination are asked of the syringe-customer participants in order to evaluate social constraints the participant has experienced in his/her lifetime. Such social constraints may adversely affect attitudes towards being HIV tested and using injection drugs.

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

**A.** This information collection will occur over a three year period. The study will consist of two populations being studied: 1) 48 adult (age >18 yrs) pharmacy staff (pharmacists and pharmacy technicians), will be surveyed on pharmacy staff attitudes and behaviors regarding HIV testing and referral; and 2) 221 adult (age >18 yrs) injection-drug-using syringe customers who will complete a brief quantitative interview after HIV referral or HIV testing is offered to them. Not all interviews are conducted every year. The Annualized Burden Table (Table 12.A) was constructed based on activities during any one year of the study. Approximately 24 pharmacists will be contacted by telephone during the first year and screened using the "Pharmacy Telephone Screening and Enrollment Form" (Attachment 5) for their eligibility to join this study. The interview will take approximately 10 minutes. Telephone screening will end when 12 pharmacies are enrolled in the study. Recruitment of pharmacies will be completed during the first year of the study.

After enrollment into the study, two pharmacists at each of the 12 pharmacies will be administered the "Pharmacy Staff Baseline Survey" (Attachment 3a) which will take approximately 20 minutes. The same form will be used for two pharmacy technicians at each of the 12 pharmacies. This will occur during the first year.

At 6, 12, and 18 months after the start of the project the "Pharmacy Staff Six Monthly Survey" (Attachment 3d) will be completed by 2 pharmacists and 2 pharmacy technicians at each of the 12 pharmacies. Each interview will take approximately 20 minutes. Table 12.A. includes burden for two 6-month surveys each year.

During the interim months when the semiannual survey is not conducted, a 10-minute "Pharmacy Staff Monthly Survey" (Attachment 3b) will be administered to 1 pharmacist in each of the twelve participating pharmacies. In all, a total of 10 monthly surveys will be conducted in the first year.

At 24-months, a 20-minute exit survey, "Pharmacy Staff Exit Survey" will be administered to 2 pharmacists and 2 pharmacy technicians at each of the participating pharmacies (Attachment 3e).

In addition to the surveys, 1 pharmacy technician at each of the 12 participating pharmacies will complete a "Syringe Transaction and Referral Log" (Attachment 3c) daily, which will take approximately 5 minutes.

A total of 442 syringe customers will be enrolled in the study. Each syringe customer that participates in the study will

complete a one-time, 30-minute “Pharmlink Participant Baseline Survey” (Attachment 3f).

Exhibit 12.A Estimate of Annualized Burden

The estimate of the annualized burden hours in Table A.12 is 415 hours.

| Respondent | Form Name | No. of Respondents | No. of Responses per Respondent | Average Burden per Response (in hours) | Total Burden (in hours) |
|---|---|---|---|---|---|
| Pharmacist | Pharmacy telephone screening and enrollment form (Att. 5) | 8 | 1 | 10/60 | 1 |
| Pharmacist and Pharmacy Technician | Pharmacy staff baseline survey (Att. 3a) | 16 | 1 | 20/60 | 5 |
| Pharmacist and Pharmacy Technician | Pharmacy staff six monthly survey (Att. 3d) | 16 | 2 | 20/60 | 10 |
| Pharmacist and Pharmacy Technician | Pharmacy staff exit survey (Att. 3e) | 16 | 1 | 20/60 | 5 |
| Pharmacist | Pharmacy staff monthly survey (Att. 3b) | 12 | 10 | 10/60 | 20 |
| Pharmacy Technician | Syringe sales and referral log (Att. 3c) | 12 | 300 | 5/60 | 300 |
| Syringe-customer study participant | Pharmlink Participant Baseline Survey (Att. 3f) | 147 | 1 | 30/60 | 74 |
| Total | | 227 | | | 415 |

**B**. Annualized cost to respondents for the burden hours is provided in Exhibit A.12.B. The average hourly wage for pharmacists and pharmacy technicians is based on wages for New York City, 2005 as provided by the NYAM/CUES. The average hourly wage for syringe exchange participants is based on overall blue-collar wages for New York City, 2005.

Exhibit A.12. B: Estimated Annualized Burden Costs*

| Respondent | Total Burden hours | Hourly Wage Rate | Total Respondent Cost |
|---|---|---|---|
| Pharmacist (Att. 5) | 1 | $41.27 | $41 |
| Pharmacist (Att. 3a) | 2.5* | $41.27 | $103 |
| Pharmacist (Att. 3d) | 5* | $41.27 | $206 |
| Pharmacist (Att. 3e) | 2.5* | $41.27 | $103 |
| Pharmacist (Att. 3b) | 20 | $41.27 | $825 |
| Pharmacy Technician (Att. 3a) | 2.5* | $20.44 | $51 |
| Pharmacy Technician (Att. 3d) | 5* | $20.44 | $102 |
| Pharmacy Technician (Att. 3c) | 300 | $20.44 | $6,132 |
| Pharmacy Technician (Att. 3e) | 2.5* | $20.44 | $51 |
| Syringe-customer study participant (Att. 3f) | 74 | $20.34 | $1,505 |
| Total | 415 | | $9,121 |
| * Shown as totals for pharmacist and pharmacy technician in Table 12.A. The costs are separated in this table due to the difference in hourly wage. | | | |

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

There are no costs to respondents other than their time.

**14. Annualized Cost to the Federal Government**

The project is funded through a Cooperative Agreement to the NYAM (PS07-003/1U01PS000698-01) for four years. The cost of the project for 4 years is estimated to be $1,180,000.

Exhibit A.14: Estimates of Annualized Costs to the Federal Government.

| Expense Type | Expense Explanation | Annual Costs (dollars) |
|---|---|---|
| Direct Costs to the Federal Government | CDC Project Officer (USPHS Commissioned Corps Officer Pharmacist, O-6, .2 FTE) | $23,767 |
| | CDC Co-Principal Investigator (GS-14, .1 FTE) | $10,780 |
| | CDC Co-Principal Investigator (USPHS Commissioned Corps Officer Medical, 0-5, .05 FTE) | $7,250 |
| Operational | Travel – two trips for Project Officer and two trips for Co-PI | $10,000 |
| | Subtotal, Direct Costs to the Government | $51,797 |
| Contractor and Other Expenses | Cooperative Agreement to New York Academy of Medicine | $295,000 |
| | | |
| | Subtotal, Contracted (CoAg) Services | $295,000 |
| | TOTAL COST TO THE GOVERNMENT | $346,797 |

Salary estimates were obtained from the United States Public Health Service Commissioned Corps Website (http://dcp.psc.gov/) and the OPM salary scale (http://www.opm.gov/).

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

This is a new data collection.

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

Exhibit A.16: Project Time Schedule

| Activity | Time Schedule |
|---|---|
| Contact Pharmacies to Participate in the Study | 1 - 2 months after OMB approval |
| Train Pharmacy Staff in Study Procedures | 2 - 3 months after OMB approval |
| Enroll Syringe-Customer Participants into the Study | 4 - 28 months after OMB approval |
| Analysis | 28 - 31 months after OMB approval |
| Dissemination of Results | 31 - 36 months after OMB approval |

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

No exception is requested.

**18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions 5CFR 1320.3(h)(1)-(10)**

No exception is requested.