SUPPORTING STATEMENT
FOR THE
Intervention Trials to Retain HIV-Positive Patients in Medical Care

HIV/AIDS Bureau
Division of Science and Policy
Health Resources and Services Administration
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SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT 1995
SUBMISSION INFORMATION COLLECTION PLAN

A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

This is a request for Office of Management and Budget (OMB) approval for the data collection as part of a clinic-based research study entitled "Increasing Retention in Care among Patient Being Treated for HIV Infection". This research is a collaboration between the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and six university-affiliated HIV clinics in the United States. The proposed data collection will occur over 4 years.

Justification for Study

Increasing the percentage of HIV-positive persons who are retained in medical care directly benefits the health of these patients. It is also an important prevention strategy for reducing transmission of HIV infection because patients in care may receive prevention services and because patients on antiretroviral therapy (ART) who have low viral loads are less likely to infect others through sexual risk behaviors. The Antiretroviral Treatment Access Study (ARTAS) demonstrated the efficacy of a strength-based case management approach in linking newly diagnosed HIV-positive persons to primary medical care (Gardner et al., 2005). However, new strategies for retaining HIV-positive patients in care are needed. CDC data suggest that 50-55% of the U.S. adult HIV-diagnosed population is not stably in care within 12-24 months of their HIV diagnosis (Glynn, 2005; Teshale et al., 2005). African Americans comprise the majority of new HIV cases in the U.S. and are less likely than whites to be stably in care (Crystal et al., 2001). Stability in care has been associated with better adherence to ART. Of HIV-positive patients who missed over 25% of their medical appointments, only 64% were using ART as prescribed compared with 78% who missed fewer appointments (Moore, 2006). Data from the ARTAS study showed that patients who had three or more HIV care visits over a 6-month period were more likely than those with fewer visits to reduce sexual risk behaviors that may transmit HIV to others (Metsch et al., 2008). Patients without an AIDS-defining condition are less likely to be stable in care: (1) Only 39% of patients without AIDS had more than one CD4 count within 24 months compared with 93% of those with AIDS (Glynn, 2005); (2) For every 100 cells increase in CD4 count, there was a 20% increase in those discontinuing HIV care within the first 6 months (Samet et al., 2003).

The findings cited above indicate that retention in care is an important issue in the clinical management of HIV-positive patients and an important issue for HIV prevention. HIV clinics would benefit greatly if they had a formal intervention program that they could use to increase patient retention in care. There have not been any randomized controlled trials testing intervention strategies that focus on retention in primary care for persons living with HIV. Prior studies have attempted to identify demographic, structural, behavioral, and psychological correlates of linkage (Anthony et al., 2007; Craw et al., 2008; Gardner et al., 2007) and retention (Coleman et al., 2007; Rumptz et al., 2007) to care among people with HIV infection.

Observational studies have also examined barriers to HIV care (Naar-King et al., 2007), and have shown that receipt of needed ancillary services (e.g., housing assistance, transportation, mental health treatment) is associated with an increased likelihood of entering and remaining in care for HIV infection (Messeri et al., 2002). Correlational studies have shown that staying in contact with HIV-positive patients through outreach is associated with increased attendance for HIV primary care (Cabral et al., 2007). The important role that medical providers may play in interventions to increase retention in care of HIV-positive patients has received attention in qualitative studies (Mallinson et al., 2007). These findings inform the design of the intervention research to be conducted.

A.2. Purpose and Use of Information

The purpose of this project is to develop, implement, and test the efficacy of an intervention designed to increase client appointment attendance among patients at risk of missing scheduled appointments in HIV clinics. Strategic goals of both HRSA (Strategic Plan: FY2005 – FY2010) and CDC (HIV Prevention Strategic Plan: Extended Through 2010) are addressed by the project. Increasing appointment attendance among patients at risk of missing scheduled appointments in HIV clinics promotes linkages to care, treatment and prevention services (CDC's short-term Milestone 3) and improvement of health outcomes (HRSA's Goal 1). The study will be conducted in six HIV clinics affiliated with (1) University of Alabama at Birmingham; (2) Baylor College of Medicine, Houston, Texas; (3) Johns Hopkins University School of Medicine, Baltimore, Maryland; (4) State University of New York, Downstate Medical Center, Brooklyn, New York; (5) Boston Medical Center, Boston, Massachusetts; and (6) University of Miami Miller School of Medicine, Miami, Florida. Findings from the project will inform administrators and primary care providers at HIV clinics of intervention activities that can be used in their clinics to increase HIV-positive patients' attendance for primary medical care.

The proposed intervention will be implemented in two phases. Clinic attendance rates will be examined in two ways to test the study hypotheses: (1) the percentage of patients who attended at least one HIV primary care visit in each of two consecutive 6-month periods during 12-month intervals, and (2) the proportion of scheduled HIV primary care clinic appointments kept during 12 months per patient. Hypotheses for the project are:

Phase 1: The attendance rate for HIV primary medical care at the six participating clinics will be significantly higher during the first 12-month clinic-wide intervention period compared with the attendance rate during the 12 months before implementing the clinic-wide intervention.

Phase 2: The attendance rate for HIV primary medical care will be significantly higher among patients who receive a client-centered intervention plus the clinic-wide intervention than among patients who receive only the clinic-wide intervention.

Phase 1 is a **clinic-wide intervention** that includes the following components: a theme slogan for the intervention, brochures, posters with messages to patients and ~~,~~ brief verbal retention in care messages from clinicians and clinic staff to patients. These materials are included in Tab 1.

Each participating site continues to use site specific~~,~~ ~~and~~ appointment reminder cards with information on how to cancel appointments. All patients in the six participating HIV clinics will receive the Phase 1 intervention. The impact of the clinic-wide intervention on HIV-positive patients' attendance for primary HIV medical care will be measured by electronically abstracting clinical data (without personal identifiers) that is routinely archived in electronic databases at the six participating clinics. Each clinic's attendance rate during a 12-month period before the start of the clinic-wide intervention will be compared with the attendance rate during the first 12 months of the intervention and with attendance during two subsequent 12-month intervention periods.

Phase 2 of the project will examine the extent to which a **client-centered intervention** delivered by trained interventionists (Retention Specialist **(RS)** and Patient Navigator **(PN)**) improves patient attendance for HIV primary care over and above the effect of the clinic-wide intervention. During Phase 2, a three-arm randomized controlled trial will be conducted in each of the participating clinics. Specifically, each clinic will enroll 300 patients. One hundred will be new patients and 200 will be established patients with inconsistent attendance (missed at least one visit) for HIV primary care in the prior 12 months. These 300 patients will be randomized to one of three intervention arms. A total of 100 patients (33 new/67 inconsistent) will be randomized to receive a comprehensive intervention, 100 (33 new/67 inconsistent) will be randomized to receive a brief intervention, and 100 (33 new/67 inconsistent) will be randomized to a control arm in which they will receive standard of care available to all patients at the clinic but no special intervention on retention to care.

Both the comprehensive and brief intervention will be delivered by the same two trained interventionists (RS and PN) and both arms will contain the same intervention elements. The difference between arms will be in the number of intervention sessions, how long each session lasts, and the comprehensiveness of the material. In the comprehensive arm, the intervention sessions will each be approximately 45-60 minutes and will occur at the clinic (1) on the day of enrollment into the study, (2) at a special intervention visit at the clinic two weeks later, and (3) and each subsequent visit for primary care at the clinic during the next nine months. In the brief arm, the intervention sessions will each be approximately 15-20 minutes and will occur at the clinic (1) on the day of enrollment into the study and (2) at each subsequent visit for primary care at the clinic during the next nine months.

In both intervention arms, patients will receive information about the importance of regular clinic attendance, motivational messages to stay in care, and modules designed to help patients increase specific skills that may improve clinic attendance (See Tabs 2 through 4 for the Skills Domain modules). Those skills include how to successfully navigate the medical system, how to resolve problems that may be barriers to clinic attendance, how to increase confidence in communicating with providers, how to use adaptive coping strategies to deal with life events, and how to organize their life in a way that includes regular attendance at clinic.

Proposed Data Collection

The proposed data collection with frequency of administration for both phases of the project will include:

Activity	Tab No.
Phase 1 and Phase 2: Electronic clinic database abstraction (records abstracted quarterly for duration of the project)	5~~1~~
Primary Care Provider Survey (Phase 1: quarterly; Phase 2: every 6 months)	6~~2~~
Clinic Staff Survey (Phase 1: quarterly; Phase 2: every 6 months)	7~~3~~
Patient Exit Survey (Phase 1 and Phase 2: every other month)	8~~4~~
Phase 2: Patient Eligibility Screener (administered one time only)	9b~~6~~
Patient Baseline Survey (administered one time only)	10~~7~~
Retention Risk Screener (administered ~~quarterly for one year~~one time only)	11~~8~~
Retention Specialist/Patient Navigator Encounter Form (Phase 2 only: once for every patient encounter)	12~~9~~
Contact/locator information (updated quarterly for one year)	13~~0~~

The proposed data collection has important utility to the government, the six sites participating in the project as well as administrators and primary care providers at HIV clinics. These data are necessary to test the efficacy of the proposed intervention in increasing client appointment attendance among patients at risk of missing scheduled appointments in HIV clinics.

Electronic clinic database abstraction

The data elements to be abstracted from clinic databases in both phases of the project are listed in the Tab 5~~1~~. Each of these elements are routinely collected and saved in electronic databases at the clinics for their own patient management purposes. During Phase 1 and Phase 2 of this project, data managers at each of the six clinics will prepare data files containing these variables on existing and new patients.

When creating these files, the sites will remove all information that can potentially identify a patient (e.g., name, social security number, medical record number used by the clinic to identify a patient). Each site will assign a unique 6-digit identification number be generated by a computer algorithm. These study ID codes will be generated by a computer algorithm at each site. The study ID code will be linked to the patient's medical record number and these identifiers will be stored in a password-protected network server at each site. The study ID code number will be the only identifying variable in the data transmittals to CDC.

Primary Care Provider Survey and Clinic Staff Survey

The purpose of these surveys is to obtain information from primary care providers and other clinic staff about whether they talked to their patients about the importance of regular care. As

noted in the previous table, surveys will be administered on a quarterly basis in Phase 1 and every six months in Phase 2. At each survey period, primary care providers and other clinic staff will be asked to complete surveys (see Tab 62 and Tab 73) that will reflect longitudinal trends in provider/staff reports of the percentage of patients to whom they delivered messages. The percentages provide cross-sectional snapshots at specific periods in time; the surveys will not reflect longitudinal trends of the same providers over time. Respondents' names will not appear on any of the surveys.

Patient Exit Survey

A brief survey (four items plus race, ethnicity and gender) will be administered to a convenience sample of patients as they exit the clinic to assess patient exposure to the theme slogan for the intervention and posters with messages to patients as well as receipt of brochures and brief verbal retention in care messages from clinicians and clinic staff. (See Tab 84) Patient Exit Surveys will be administered every other month (six times per year) to 50 patients in each of the participating clinics. Surveys will be voluntary, anonymous and conducted in private arranged by the participating clinics.

Patient Eligibility Screener

The eligibility criteria for Phase 2 of the project are presented in Tab 9a5. Phase 2 participants will be enrolled over a 4-9 month period to allow some flexibility for differences in the rate of enrollment among the participating clinics. It is anticipated that most clinics will complete their enrollment in approximately 6 months. To enroll participants, clinic staff or a study coordinator will use the appointment logs for each clinic session to generate a list of patients who meet eligibility criteria based on attendance history. Using the list of eligible patients, the study coordinator will approach the listed patients in the waiting room and ask about the patient's interest in being screened for eligibility in the study. The Patient Eligibility Screener will be used to determine if the patient meets study eligibility criteria. (See Tab 9b6) A script for introducing the study to prospective participants appears at the top of the eligibility screener. The form will be completed for all patients approached. Eligible patients are asked if they are willing to participate in the study and if they agree to participate, informed consent is obtained. Patients who decline screening or eligible patients who decline to enroll are asked a few brief items to document why a patient declines to participate. These data will be used to examine participation rates and reasons for refusal.

Patient Baseline Survey

All enrollees will complete a baseline survey that will take approximately 30 minutes before being randomized to the intervention or control arm. No follow-up surveys will be collected. The survey will be administered in a private setting at the clinic using Audio Computer-Assisted Self-Interview (ACASI) in which respondents can read and listen via earphones to survey questions presented on the computer screen and respond directly into the computer. The survey is written at a 7.0 reading level. The survey will identify attitudes, barriers, co-morbidities and unmet needs that might prevent a patient from staying in care. The general domains of the survey are listed below and the full instrument appears in Tab 107.

- Demographics
- Health-related quality of life
- History of HIV care
- Adherence to antiretroviral therapy
- Use of drugs
- Use of alcohol
- Incarceration
- Mental health
- Structural and financial barriers
- Unmet needs
- Social Support
- HIV Stigma
- Life chaos
- Patient assessment of medical providers

The Patient Baseline Survey will be available in English, Spanish and Creole. A translation/ back translation process will be utilized to ensure consistency between English, Spanish and Creole versions. All procedures and instruments, including consent forms will be piloted and field tested. Separate pilot and field test activities will be undertaken for the ACASI survey. Each pilot activity will involve 10 patients at each site for a total of 60 ACASI survey pilots.

Retention Risk Screener

Interventionists will administer the retention risk screener (see Tab 118). This screener is a clinical tool that will help identify attitudes, barriers, and unmet needs that might prevent a patient from staying in care. The screener contains three sections: (1) attitudes and beliefs about HIV care and treatment, (2) barriers to consistent clinic attendance (e.g., transportation, child care, housing instability, scheduling problems, and lack of social support), and (3) recent drug/alcohol use and mental health. Interventionists will use the information obtained from the risk screener to tailor the intervention to each individual patient. ~~Because a patient's situation or needs may change over time, the screener will be re-administered to intervention arm participants during a clinic visit or other arranged face-to-face meetings outside of the clinic at approximately 3-months intervals.~~ Unmet needs and barriers to care obtained from the risk screener may be shared with other clinical staff or included in the patient's medical chart to ensure continuity of care.

Retention Specialist/Patient Navigator Encounter Form

The interventionists will complete an encounter form documenting all time spent directly with or on behalf of intervention arm participants (see Tab 129). The encounter form will document the time spent and activities completed during the following types of encounters: (1) face-to-face intervention sessions, (2) telephone, mail, or e-mail contacts, and (3) interactions between the RS and PN, RS and case manager(s), and RS and medical team on behalf of intervention participants. The RS and PN will complete paper versions of the encounter forms (that will include the Phase 2 study ID code but not the medical record number) for each encounter with a

participant. The completed hardcopy forms will be kept by the RS/PN team and filed in a locked cabinet dedicated exclusively to the study.

Contact/locator information

This information (see Tab 13~~0~~) will only be obtained from participants in the intervention arms. The information will be obtained by the study coordinator after randomization and before being introduced to the interventionists. Contact information will be updated periodically (approximately 4 times per year). Patients will be explicitly asked if it is okay to contact them by telephone or e-mail, by going to their home or to places they hang out, or by contacting another person who knows them well. They will be asked if it is okay to leave a general voice mail message (that does not mention HIV medical care). Patients will also be asked to provide contact information for Community Based Organizations (CBOs) or AIDS Service Organizations (ASOs) in the community from which they receive services. This contact and locator information collected as part of the study will remain exclusively with the intervention team in hardcopy form and will be stored in a locked cabinet in the interventionists' office. The contact/locator information will not be sent to HRSA or CDC and will be destroyed within one month after the Phase 2 of the project ends.

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

Collection/abstraction of data from the ***Electronic clinic database*** and ***Patient Baseline Survey*** will rely on electronic technology.

Electronic clinic database abstraction

All six clinics participating in the project have established electronic databases for patient management purposes. These databases include electronic health information. The project data manager will electronically abstract the required patient attendance and HIV clinical data from these databases. The abstracted data will be archived on a password-protected area of a network server at each medical center. The data manager at each site also will be responsible for transmitting these data files to CDC. Only the data manager and other authorized study staff will have access to any linked database (i.e., database that includes medical record number and study ID number). The data files sent to CDC will include only numeric values corresponding to the 25 data elements in Tab No. 5~~1~~ including the unique numeric study code number. All other information that the sites may potentially use to assign unique study code numbers (e.g., medical record number) will be stripped before being forwarded to CDC. Neither CDC nor HRSA will receive any information that will enable them to link a patient's study code number with any personally identifying information.

Patient Baseline Survey

Patients enrolling in Phase 2 of the project will complete the ***Patient Baseline Survey*** in a private setting at the clinic using Audio Computer-Assisted Self-Interview (ACASI) in which respondents can read and listen via earphones to survey questions presented on the computer

screen and respond directly into the computer. The ACASI program includes skip instructions to transition the respondent to applicable questions based on prior responses. The respondent enters a response directly into the computer through a touch screen or number keypad. Before beginning the survey, the participant will complete a short ACASI tutorial that demonstrates the types of questions and responses in the survey. After the tutorial is completed, the coordinator will inform the participant that he/she will be available in an adjacent room or nearby area to help with any questions or problems that arise and then will exit the room. Use of ACASI will minimize burden and protect privacy.

The ***Primary Care Provider and Clinic Staff Surveys, Patient Exit Surveys, Patient Eligibility Screener, Retention Risk Screener, Retention Specialist/Patient Navigator Encounter Form,*** and ***Contact/locator information*** will be collected on paper forms.

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

Although the important role that medical providers may play in interventions to increase retention in care of HIV-positive patients has received attention in qualitative studies (Mallinson et al., 2007), there have not been any randomized controlled trials testing intervention strategies that focus on retention in primary care for persons living with HIV. Prior studies have focused on linkage to care and have examined demographic, structural, behavioral, and psychological factors that are related to entering care among people with HIV infection.(Anthony et al., 2007; Craw et al., 2008; Gardner et al., 2007) and retention (Coleman et al., 2007; Rumptz et al., 2007) to care. Studies examining the barriers to HIV care have shown that receipt of needed ancillary services (e.g., housing assistance, transportation, mental health treatment) is associated with an increased likelihood of entering and remaining in care for HIV infection (Messeri et al., 2002; Naar-King et al., 2007)). As previously noted, correlational studies have shown that staying in contact with HIV-positive patients through outreach is associated with increased attendance for HIV primary care (Cabral et al., 2007). These findings inform the design of the intervention research to be conducted.

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

No small businesses will be involved in this study. Further, the study will not impact small businesses, including health departments, non-profit organizations, dentist or physicians' offices, or CBOs.

A.6. Consequences of Collecting the Information Less Frequently

This is a one-time collection. Collection of less information with a smaller sample would reduce the ability to understand the impact of the Phase 1 and Phase 2 interventions on increasing clinic appointment attendance among patients at risk of missing scheduled appointments in HIV clinics. The proposed information collection assess: (a) provider delivery of the proposed interventions; (b) patient receipt of the interventions; (c) patient attitudes, barriers, co-

morbidities and unmet needs that might prevent a patient from staying in care; and (d) changes clinic attendance rates over time.

A.7. Consistency With the Guidelines in 5 CFR 1320.5(d)(2)

There are no special circumstances relating to the guidelines of CFR 1320.5(d)(2).

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

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The 60-Day-Notice as required in 5 CRF 1320.8(d) was published in the Federal Register on December 24, 2008, Vol. 73, No. 248, pages 79134-35. (See Tab No. 14~~1~~.) No public comment was received from this notice.

The development of the research design, interventions and data collection instruments for this project has been a collaborative effort among HRSA, CDC and the six participating HIV clinical sites. Since January 2008, bi-weekly conference calls that included the principal investigators, project directors and data managers as well as Federal staff have been conducted. In addition, two workgroups were formed to develop the Phase 1 clinic-wide intervention and the Phase 2 client-centered intervention. Throughout the development of the project, the individual participating sites have consulted with their clinic's Consumer Advisory Committees to get input from the patients' perspective.

The following individuals have reviewed the instruments developed for the project:

Instrument Reviewers
Houston, TX Baylor College of Medicine Thomas P. Giordano, MD, MPH, Principal Investigator
Boston, MA Boston Medical Center Paul R. Skolnik, MD, Co-Principal Investigator Boston U. School of Public Health Mari-Lynn Drainoni, PhD, MEd, Co-Principal Investigator
Baltimore, MD Johns Hopkins University School of Medicine Richard D. Moore, MD, MHSc, Principal Investigator Jeanne Keruly, MS, CRNP, Co-Investigator
Brooklyn, NY The Research Foundation of State University of New York (SUNY) SUNY Downstate Medical Center Tracey E. Wilson, PhD, Principal Investigator
Birmingham, AL University of Alabama at Birmingham Michael S. Saag, MD, Principal Investigator Michael J. Mugavero, MD, MHSc, Co-Investigator
Miami, FL

Instrument Reviewers
University of Miami Miller School of Medicine Allan E. Rodriguez, MD, Principal Investigator Lisa Metsch, PhD, Co-Principal Investigator

A.9. ~~Remuneration~~ Incentives ~~of~~ for Respondents

The respondent is viewed as an integral partner in the research process. Provision of an honorarium can help to increase response rates and avoid biases resulting from the omission of those who decline participation because it would take them away from other tasks, in particular those that generate income [Thompson 1996]. Moreover, an honorarium that takes into account the duration of participation and the procedures involved helps to demonstrate respect and appreciation for the respondent's role in the research process [Grady 2001; Grady 2005]. Participants will receive $20 ~~to $30~~ in cash equivalent (e.g., gift card) for their time spent completing the baseline ACASI survey. Payment will be made immediately after participants complete the patient surveys (as opposed to paying them after the intervention session) to prevent participants from thinking that they are being paid to see the interventionists.

A.10. Assurance of Confidentiality

The research protocol for this project has been granted approval by Institutional Review Board (IRB) at the Centers for Disease Control and Prevention. (See Tab 12) Each of the participating sites has been granted IRB approval by their respective institutions for Phase 1 of the project. IRB approval for Phase 2 will be obtained prior to implementation.

Informed Consent

Phase 1 and Phase 2: Transmittal of medical and attendance data to CDC. A waiver of patient authorization to use protected health information (PHI) in health research will be requested. This waiver applies to the transmittal of patient attendance data, demographic information, and HIV medical data from clinic databases during Phase 1 and 2. Each study site will apply for the necessary HIPAA waiver from their local IRBs concerning the transmittal of PHI.

Phase 1 and Phase 2: Delivery of clinic-wide intervention to patients. It is important for all patients to receive the clinic-wide intervention because that focuses on the importance of regular care. A waiver of informed consent is being requested for the delivery of the clinic-wide intervention to all patients (giving patients a brochure and messages about the importance of regular clinic attendance; hanging supportive posters in the waiting room and exam rooms; having clinic staff and providers wear buttons displaying the theme of the intervention). This research component meets criteria in 45 CFR 46.116(d) to waive informed consent.

Phase 1 and Phase 2: Serial provider surveys. A waiver of informed consent is requested for the provider surveys conducted during Phase 1 and Phase 2 as the data collection meets requirements of 45 CFR 46.116(d). Providers will be asked to complete surveys periodically during Phase 1 and Phase 2. These surveys pose minimal risk. The surveys will not contain providers' names and not ask any personally invasive questions. The surveys will include the last two digits of the provider's social security number and a number reflecting the month they were born. This information will be used to link an individual's surveys across time, but this information, by itself, will not identify specific providers. Providers will put their completed survey in sealed envelopes and return them to the study coordinator. After all surveys are collected during a

specific assessment period, the study coordinator will remove the completed surveys from their envelopes and place them in a FedEx box (or other carrier) to be sent directly to CDC for data processing.

Phase 2: Informed Consent for Participation in the RCT. At all six clinics, informed consent will be administered in person at the clinic after the candidate is determined to be eligible to participate. A copy of the informed consent will be given to the patient and he/she will be asked to follow along as the form is read aloud by the study coordinator. Those who agree to participate will sign and date three copies of the consent. Each copy will be signed and dated by a witness (study coordinator). One copy will be given to the participant, another will be filed in the medical record, and the final copy will be stored in a locked cabinet at the research site. The consent document (See Tab 163) written at a 7th grade reading level, will be available in English, Spanish, and Creole. The English Language consent will be translated into Spanish and Creole and then back-translated to identify and correct any ambiguities in meaning. Not all of the clinics will need a Creole language consent form.

Protection of Participant Records

Participating sites are collectively applying for a Federal Certificate of Confidentiality, which will be obtained in January 2010.

Transmittal of Data

All project data will be transmitted to CDC through a Secure Data Network (SDN). The process for transmitting data will be as follows: authorized study staff will access their site's password-protected area on a server in order to transmit the data files through the Secure Data Network (SDN) to CDC. No personally identifying information will be transmitted. The SDN encrypts and prohibits any modification of data in transit between the local project site and CDC. The SDN assures that only project sites can deliver and retrieve authorized information from CDC servers.

A.11. Justification for Sensitive Questions

In order to better understanding and identify attitudes, barriers, co-morbidities and unmet needs that might prevent a patient from staying in care, it is necessary to ask sensitive questions about substance and alcohol use, incarceration history, mental health, structural and financial barriers to care, unmet needs, social support, HIV stigma and life chaos. As part of the informed consent process, respondents will be fully informed of the voluntary nature of the study and their right to skip questions that they do not wish to answer.

A12. Estimates of Annualized Hour Burden

The table below reflects the total estimated annualized respondent burden hours for the study.

Type of Form by Phase	Number of Respondents	Number of responses per respondent	Total Responses	Average burden per response (in hours)	Total Burden (in hours)	Wage Rate	Total cost (in hours)
Phase 1 Primary Care Provider Survey	150	4	600	0.167	100	$62.11	$6211.00
Clinic Staff Survey	270	4	1,080	0.167	180	$14.74	$26538.20
Patient Exit Survey	1,800	1	1,800	0.033	60	$9.08	$544.80
Electronic data abstraction	6	4	24	40.0	960	$35.32	$33907.20
Phase 1 Burden	2,226		3,504		1,300		$433162.20
Phase 2 Primary Care Provider Survey	150	2	300	0.167	50	$62.11	$3105.50
Clinic Staff Survey	270	2	540	0.167	90	$14.74	$1326.60
Patient Exit Survey	1,800	1	1,800	0.033	60	$9.08	$544.80
Patient Eligibility Screener*	3,000	1	3,000	0.083	249	$9.08	$2260.92
Pilot test for Patient Baseline Survey*	60	1	60	0.50	30	$9.08	$272.40
Patient Baseline Survey*	1,800	1	1,800	0.50	900	$9.08	$8,172.00
Retention Risk Screener*	1,200	14	4,8001,200	0.25	1,200300	$9.08	$10896.002,724.00
Retention Specialist/Patient Navigator	12	300	3600	0.017	61	$23.16	

Encounter Contact/locator information	1,200	4	4,800	0.083	398	$9.08	$1412.76 $3613.84
Electronic data abstraction	6	4	24	40.0	960	$35.32	$33907.20
Phase 2 Burden	98,4923~~8~~		172~~0~~,1266~~6~~ 4		3,968		$~~65~~239.6~~2~~57,340.02
Total Burden	**11,726~~6~~4**	**…….**	**204,~~1~~628**	**…….**	**5,268**		**$1008,656.225~~61~~**

*Only administered one time during the entire project period.

Estimated Annualized Burden Costs

The table below presents the estimated annualized burden costs. It is estimated that 50 percent of the primary care provider respondents will be physicians with an hourly wage of $84.97 and the remaining primary care providers will be physician assistants, nurse practitioners or nurses with an hourly wage of $39.24. Using these figures, the average hourly wage rate for all primary care providers is $62.11. An average hourly wage of $14.74 associated with healthcare support workers is used for clinic staff and an average hourly wage of $35.32 for computer programmers is used for the electronic data abstraction. The majority of the patient respondents will be of lower socioeconomic status. If employed, most will be in service-related jobs with an estimated average hourly wage of $9.08. All estimated of hourly wage rates are based on Bureau of Labor Statistics, National Occupational Employment and Wage Estimates for the United States (May 2008).

A.13. Estimates of Annualized Cost Burden to Respondents

There are no direct costs to respondents other than their time to participate in the data collection. A one time only cost burden of $3600 per site (total for six sites = $21,600) for three laptop computers per site is estimated.

A.14. Estimates of Annualized Cost to the Federal Government

The five-year project is being be conducted through individual contracts with the six participating HIV clinics affiliated with (1) University of Alabama at Birmingham; (2) Baylor College of Medicine, Houston, Texas; (3) Johns Hopkins University School of Medicine, Baltimore, Maryland; (4) State University of New York, Downstate Medical Center, Brooklyn, New York; (5) Boston Medical Center, Boston, Massachusetts; and (6) University of Miami Miller School of Medicine, Miami, Florida. The total cost of the six contracts for the entire project is $8,970,211. The annualized cost of these awards as well as the annualized federal cost to support HRSA Project Officer and Investigators, CDC-based project officers and a study coordinator is given in the table below.

Annualized Costs to the Federal Government

Title	Federal salary grade	Salary	% effort	Annualized cost
6 contractors (clinic sites)	-			$1,794,042.00
CDC Project Officer	GS 14-10	$128,607	80%	$102,885.60
CDC Co-Project Officer	GS 14-10	$128,607	50%	$64,303.50
CDC Study Coordinator (contractor)	NA	$60,320	80%	$48,256.00
HRSA Project Officer	GS 15-8	$149,029	15%	$22,354.35
HRSA Investigator	SES	$193,000	2.5%	$4,825.00
HRSA Investigator	GS 13-6	$101,416	20%	$20,283.20
Total annualized cost				$2,056,949.65

A.15. Explanation for Program Changes or Adjustments

This is a new collection of information.

A.16. Time Schedule, Publication and Analysis Plans

Statistical Analysis

Phase 1: Prior to the substantive analyses, all variables will be examined for missing data, outliers, and distributional properties.

The analysis will focus on two main dependent variables during a 12-month period: (a) the percentage of patients who have attended at least one visit for HIV primary care in each of two consecutive 6-month intervals; and (b) the proportion of scheduled appointments for HIV primary care kept by a patient.

Measure “a” above will be analyzed as a dichotomous variable. Patients who have attended at least one visit for HIV primary care in each of two consecutive 6-month intervals will be coded “1” (well engaged in care~~consistent attendees~~) and those who do not fulfill this definition will be coded “0” (not well engaged in care~~inconsistent attendees~~). In univariate analysis of this

dichotomous outcome measure, the McNemar test will be applied. Assuming a cohort of 10,000 active patients pooled across the six clinics (as described in the power analysis section (See Section B.2.), the percentage of patients who were consistent attendees in the 12-month pre-intervention period and the percentage who were consistent attendees during the 12-month intervention period will be examined. The 2 x 2 table for categorizing the patients is seen below.

	First 12 months of the intervention		
12-month pre-intervention period		Inconsistent attendees	Consistent attendees
	Inconsistent attendees	a	b
	Consistent attendees	c	d

The results of the McNemar's test are distributed as a chi-square. However, the data are not independent samples so an adjustment must be applied to the X^2 calculation. Eliaszaw and Donner (1991) propose a solution that takes into account the correlation of behavior over time and is represented by an intraclass correlation (ρ) applied to the X^2:

$$X^2_{1d.f.} = [(b-c)^2/b+c]/1+ \rho$$

This approach will be used in several iterative analyses of the data. First, as shown in the table above, change from pre-intervention period to the first 12 months of the intervention will be examined. Second, the intervention will continue during Phase 2 of the project. Thus, longer-term effects will be examined by comparing the pre-intervention period with the second 12 months of the intervention (omitting patients who have been enrolled in the Phase 2 randomized controlled trial scheduled to begin during the second 12-month period). Third, a series of stratified analyses will be performed to examine the consistency of the intervention effect by clinic, sex of patient, ethnicity, age, HIV exposure risk category, and HIV clinical status of patient (CD4 and viral load).

The dichotomous outcome measure will also be analyzed in multivariate models using repeated measures logistic regression analyses that adjust for the correlation of patients' behavior over time and adjust for the correlation (i.e., clustering) of patients' behaviors within clinics. These models will be conducted using generalized estimating equations (GEE) with a binary error term. In these analyses, we will have data from a 12-month pre-intervention period as well as two 12-month intervention periods. Thus, we will be able to examine the trends over time in percentage of consistent attendance, statistically controlling for clinic site as well as demographic factors and HIV clinical status of patients. Additionally, we plan to conduct stratified logistic analyses to examine whether the intervention had comparable effects in different subgroups (e.g., each of

the six clinics, men, women, younger and older patients, patients whose CD4 levels are below 200 or higher).

Measure "b" above (the proportion of scheduled appointments for HIV primary care kept by a patient) is a continuous outcome measure. It is sensitive to small improvement in a patient's attendance. Assume that a patient kept two of four scheduled clinic appointments for HIV primary care in the 12-month pre-intervention period and kept three of four scheduled appointments in the first 12 months of the intervention. A score reflecting that this patient kept 50% of scheduled appointments in the first 12 month period and 75% (.75 proportion) in the following 12-month period will be calculated. Theoretically, patients may have proportion scores ranging from 0 to 1. With this type of continuous dependent variable, a linear GEE regression model (adjusting for correlated data and clustering by clinic) will be used to examine changes in these proportion scores before and after exposure to the intervention. This analysis will be done using data pooled across clinics and using data stratified by clinic, demographic factors, and HIV clinical status variables.

Phase 2

The participants in each arm will be characterized on demographic, behavioral, social, and structural dimensions using data collected with the baseline ACASI survey. This information will be used to assess the initial comparability of the intervention and control arms.

The statistical analysis of the Phase 2 trial will compare the control arm (clinic-wide intervention only), the comprehensive intervention arm, and the brief intervention arm on two primary outcome measures during a 12-month period: (a) the percentage of patients who have attended at least one visit for HIV primary care in each of two consecutive 6-month intervals; and (b) the proportion of scheduled appointments for HIV primary care kept by a patient. Comparisons of the three arms will be made after the 12-month intervention period and will focus on attendance behavior during that 12-month interval.

In the simplest analysis, the percentage of consistent attendees (e.g., those who had at least one HIV primary care visit in each of two consecutive 6-month periods in the past 12 months) in the will be compared across the three arms. This will be an intention-to-treat analysis. Under the intention-to-treat scheme, individuals who received no "doses" (i.e., were never seen or heard from again by the interventionists after the initial assignment to arms) would be included in the analysis of intervention effects. The three intervention arms will be compared using regression techniques (GEE models) that control for clinic effects (i.e., clustering of patient behavior within clinic). Additional models will be conducted that examine for differences in intervention effects by clinic, by participant demographic characteristics, by patient behaviors (e.g., drug or alcohol use), and by other variables (e.g., mental health status, social support, unmet needs). This will be done by modeling interaction terms (intervention x variable) in the regression equation.

Additional comparisons of the three arms will use a continuous score reflecting the proportion of scheduled appointments for HIV primary care kept by a patient in the past 12 months. The general analytic approach will be similar to that described above for the discrete outcome measure except that a linear GEE regression model will be used.

Secondary analyses will take a more "as-treated" approach to the data and attempt to estimate the effect of "doses" of the intervention among participants in the intervention arm. Using different measures of dose, such as number of encounters with the interventionists and duration of encounters a dose-response analysis will be performed.

Additional analyses will take advantage of the ACASI baseline survey data. If the intervention and control groups should not be fully comparable at baseline on background variables relevant to the analysis, those measured variables will be included in the statistical model to eliminate their potentially confounding effects. Data from the ACASI will also be used to examine correlates of primary care attendance apart from any intervention effects. Further, the ACASI variables on demographics, barriers to care, drug use, attitudes toward providers, and other domains will be used to examine for effect modification, that is, whether the intervention had stronger or weaker effects in specific sub-groups of participants. As mentioned above, this will be tested by modeling interaction terms (intervention x variable) in the analyses.

Project Time Schedule	
Activity	**Time Schedule**
Phase 1: Clinic-wide Intervention	1-36 months after OMB approval
Phase 2: Client-centered Intervention	12-36 months after OMB approval
Data transmittals to CDC and data cleaning	2-36 months after OMB approval
Create final aggregated dataset	36 months after OMB approval
Data analysis	18-36 months after OMB approval
Presentations of findings	24-36 months after OMB approval
Manuscript preparation	36-48 months after OMB approval

A. 17. Exemption for Display of Expiration Date

The OMB expiration date will be displayed.

A. 18. Certifications

No exceptions to certification for Paperwork Reduction Act submissions are being requested