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

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B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1. Respondent *Universe and Sampling Methods*

The respondent universe is all adult HIV-positive patients receiving HIV primary medical care in the six participating clinics: 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.

In Phase 1, patients are not recruited or enrolled in the study. Rather, all patients seen in the participating clinics receiving the retention in care intervention. Archived data at the clinics reflecting patient attendance and HIV clinical status will be used in the study. Data for approximately 14,600 patients from the six clinics during a 24-month period (12-month pre-intervention period plus 12-month intervention period) will comprise the overall dataset (based on 2006 estimates from the six participating clinics). Of this total, approximately 11,000 will be established patients (already enrolled at the clinic) and 3,600 will be new patients enrolled at the clinics during the 24-month period.

In Phase 2, patients 18 years of age and older (19 years of age in Alabama) who meet one of the following criteria are eligible to enroll: (1) new patients (first or second care visit at the clinic if clinics have an intake visit); or (2) patients who have inconsistent attendance for HIV primary care (defined as having had at least one no-show for a primary care appointment in the prior 12 months and patients not seen for HIV primary care at least once in each of two consecutive 6-month periods (among persons who have been patients at the clinic for at least 12 months). Study eligibility criteria can be found in Tab No. 5. A total of 1800 patients (300 per participating clinic) will be enrolled.

Enrolling Patients into the Study

Participants will be enrolled in Phase 2 during 4-9-months timeframe to allow some flexibility for faster or slower enrolling clinics. We anticipate that most clinics will complete their enrollment in approximately 6 months. Each day, clinic staff or the study coordinator will generate a list of patients who meet eligibility criteria based on attendance history. The list will be given to the study coordinator. At most clinics, the study coordinator will approach patients in the waiting room and ask about the patient's interest in being screened for eligibility in the study. At some clinics, the patient's primary care provider will ask the patient if he/she is interested in talking with the study coordinator to learn more about the study. Each clinic will apply for the relevant HIPAA waiver for access to patient attendance history. Patients who are approached and interested in participating but cannot enroll that day due to time constraints will be asked if they would be willing to come back to the clinic to participate. For those who answer

affirmatively, a day/time will be scheduled for them to return to be consented and enrolled.

B.2. Procedures for the Collection of Information

Patients are not recruited or enrolled in the Phase 1 evaluation. Rather, archived data at the clinics reflecting patient attendance and HIV clinical status will be used in the evaluation. Data from approximately 14,600 patients from the six clinics during a 24-month period (12-month pre-intervention period plus 12-month intervention period) will comprise the overall dataset (based on 2006 estimates from the six participating clinics). Of this total, approximately 11,000 will be established patients (already enrolled at the clinic) and 3,600 will be new patients enrolled at the clinics during the 24-month period.

For the purpose of conducting the power analysis, 1,000 of these 11,000 established patients were removed due to anticipated death or out-migration. New patients who enrolled during the 24-month period were not included. Thus, the power analysis was conducted on a cohort of 10,000 patients who enrolled at the clinic before the 12-month pre-intervention period began.
As seen in the table below, the Phase I power calculation for the before-after clinic-wide intervention shows 99% power to detect a difference as small as 10% in clinic attendance rates when comparing attendance rates before the intervention with the attendance rates after the intervention.

Description	Baseline rate	Follow-up rate		Sample size	Output power
10% improvement in consistent clinic attendance	0.6	0.66		10,000	0.99

Source: McNemar's Test for Dependent Proportions. Power and Precision Software: Version 2.0. Biostat, Inc., 14 North Dean Street, Englewood, NJ 07631

Inputs: baseline rate of consistent HIV clinic attendance: 60%
Inputs: rate of HIV clinic attendance following Phase I intervention: 66%
Inputs: Type 1 or alpha error of 5%
Inputs: smallest difference that is scientifically meaningful to detect: 10%
Inputs: Sample size of all six clinics combined, assuming the same clinic patients are being compared in the 'before' condition and the 'after' condition.
Outputs: Power: 1 minus (Type 2 error probability), based on a 2-tailed test of a 10% difference (0.6 vs. 0.66) between the before and after conditions.

In the power analysis for Phase 2 in the table below, the proportion reflects the proportion of consistent attendees (at least one HIV primary care visit in each of two consecutive 6-month periods during the 12-month intervention period). The Phase 2 power calculation for a randomized trial of a patient-centered intervention shows 81% power to detect a

difference as small as 15% in clinic attendance rates between the Comprehensive intervention arm (N=600) and the Brief intervention arm (N=600).

Description	Baseline rate	Follow-up rate		Sample sizes	Output power
15% 3-arm with 600 to 600 head-to-head (compares Comprehensive arm to Brief arm)	0.6	0.69		600/600	0.81

Source: J. Fleiss, A. Tytun and H. Ury. A simple approximation for calculating sample sizes for comparing independent proportions. (1980); Biometrics 36: 343-346.

Inputs: baseline rate of consistent HIV clinic attendance: 60%
Inputs: rate of HIV clinic attendance following Phase I intervention: 69%
Inputs: Type 1 or alpha error of 5%
Inputs: smallest difference that is scientifically meaningful to detect: 15%
Inputs: Head to head comparison of Comprehensive intervention arm (N=600) vs. Brief intervention arm (N=600)
Outputs: Power: 1 minus (Type 2 error probability), based on a 2-tailed test of a 15% difference (0.6 vs. 0.69) between the comprehensive and minimal arms.

Data Transmittals, Security, and Quality Control

Per Federal guidelines, any potentially identifying information collected at the project sites will be stripped from the data before forwarding to CDC. Each site will use an account with CDC's Secure Data Network (SDN) to assure the safe transfer of data to CDC. The SDN encrypts and prohibits any modification of data in transit between the local study site and CDC. The SDN assures that study sites can only deliver and retrieve authorized information from CDC servers. Data will be stored on a secure drive at CDC that is backed up daily.

Sites will transmit updated ACASI questionnaire data and data from study forms (eligibility screener, participant status form, retention risk screener, and RS/PN encounter form) on a bi-weekly basis (i.e., every two weeks) via the SDN. CDC will merge the site-specific data files into a master database. Site-specific datasets will be retained as back-up. The patient attendance and HIV medical data will be sent to CDC beginning in Phase 1 and will continue to be uploaded to the SDN on a quarterly basis.

The data manager at each study site will complete a bi-weekly data entry control sheet that will indicate all the records that have been newly entered or updated in the databases (ACASI survey database or study forms database). The data control sheets will be forwarded to CDC at the time of a data transmittal. The data manager at CDC will check the control sheets in relation to the records received in the database upload to ensure that the information matches. Any discrepancies will be resolved through e-mail or telephone calls with the study site data manager.

The following safeguards will be in place:

- Participant names will not be included in any database sent to CDC
- Medical record numbers will not be included any database sent to CDC
- The master list of study participants will remain at the local sites and not be sent to CDC
- Locator information obtained among the intervention participants will be retained at the local sites and not sent to CDC
- All project computers at the local sites and at CDC will be password-protected. Data will be stored in restricted network drives at each project site and at CDC

Settings for Collecting the Data

All participating sites will identify a private and secure space within their clinic to administer the ACASI ***patient baseline survey*** and the ***patient exit interviews.*** The ***Primary Care Provider*** and ***Clinic Staff Surveys*** will be completed at provider and staff work stations and the ***Patient Eligibility Screener, Retention Risk Screener, Retention Specialist/Patient Navigator Encounter Form,*** and ***Contact/locator information*** will be completed within the offices/work areas assigned to the Retention Specialist and Patient Navigators.

B.3. Methods to Maximize Response Rates and Deal with Non-response

The computer-administered survey will increase response rates and decrease non-response to survey items. First, the respondent will hear each question being asked through headphones and will also see the printed question and response categories on the computer screen. Second, each respondent will receive a tutorial on using the ACASI, including the types of response scales in the survey and how to make a response. They will be given several practice items. Third, the ACASI will include programmed skip patterns to smoothly transition the respondent to applicable questions. Fourth, the program will also include validity checks to assure the logical consistency of responses, thus maximizing the number of items on which valid data will be collected. Fifth, questions do not include a "don't know" response category unless a "don't know" response is a meaningful answer. Although each question does have a "refuse to answer" option, which is mandated for all federally sponsored surveys, prior studies that have used ACASI have had few cases of refusals even on questions asking about sexual behavior. (Gardner et al., 2006)

B.4. Tests of Procedures

All instruments will undergo a translation/back translation process 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.

B.5. Statistical Consultants

Individuals consulted on statistical aspects of the study design
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LIST OF ATTACHMENTS

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