HIV Outpatient Study (HOPS)

Supporting Statement A

OMB No. 0920-New

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• Goal of the study (e.g., determine behavioral factors that influence changes in weight over time or evaluate program delivery processes)

The goals of the HIV Outpatient Study (HOPS) are to: describe and monitor trends in demographics, symptoms, diagnoses, treatments, risk behaviors and disease outcomes among HIV-positive outpatients in clinics across the United States; to describe factors associated with clinical, immunologic and virologic successes, as well as improved survival; and to investigate new problems associated with long-term HIV infection and treatment.

• Intended use of the resulting data (e.g. , provide suggestions for improving community-based programs)

HOPS data will be used to develop guidelines and recommendations for clinicians, public health departments, and other partners participating in the prevention and treatment of HIV/AIDS. It will also be used to monitor the progress in achieving the goals of the National HIV/AIDS Strategy.

• Methods to be used to collect (e.g., prospective cohort design; randomized trial; etc.)

HOPS has a prospective cohort design and will collect data by medical record abstraction and using a brief Telephone Audio-Computer Assisted Self-Interviewing (T-ACASI) survey and an identical web-based Audio-Computer Assisted Self-Interviewing (ACASI), accessible via tablet, smartphone, PC or laptop.

• The subpopulation to be studied (e.g., school-age children in North Carolina)

The HOPS study population is a demographically diverse cohort of HIV-infected adult outpatients seen at 9 well established public and private HIV clinics in the United States.

• How data will be analyzed (e.g., logistic regression)

The data will be analyzed by a variety of methods most appropriate for the research questions and variables collected (e.g., continuous versus categorical variables). Statistical analyses will include simple descriptive statistics, linear regression and logistic regression.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

The Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of HIV/AIDS Prevention (DHAP) requests a 3-year approval for a new data collection called "HIV Outpatient Study (HOPS)." The purpose of this project is to (1) describe and monitor trends in demographics, diagnoses, treatments and disease outcomes; (2) describe factors associated with clinical, immunologic, and virologic successes and improvements in survival; (3) characterize emerging problems associated with long term HIV infection and its treatment; and (4) describe HIV risk behavior and other health risk behaviors (e.g. tobacco use, adherence to antiretroviral therapy) among HIV infected patients in care. This ongoing data collection activity at 9 HIV clinics in the United States benefits the Federal Government by providing the CDC with data to determine how to best manage and improve the health of HIV-infected Americans who receive HIV care, and to monitor the progress in achieving the goals of the National HIV/AIDS Strategy (White House, 2010):

This proposed information collection is authorized under Section 301(a) of the Public Health Services 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**)

Rational allocation of resources for the treatment and care of persons with HIV infection depends on current knowledge about patient outcomes, characteristics, conditions, and current therapy of HIV-infected persons. This is not always easy to achieve; particularly regarding persons early or midway through HIV disease progression, usually being seen and treated out-of-hospital. Access to reliable and up-to-date information that integrates demographic,

clinical, and behavioral measures for the majority of HIV-infected patients cared for on an outpatient basis is needed for the effective utilization of health resources.

Studies of HIV infection in persons receiving regular outpatient medical care have been critical to the formulation of guidelines for treatment as well as for secondary prevention and treatment of conditions related to HIV/AIDS. This type of research has formed the backbone of many treatment and prevention guidelines published by the U.S. Public Health Service, the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and professional medical societies. These guidelines include recommendations regarding the initiation, use, and appropriate modification during treatment with highly active antiretroviral therapy (HAART), and the treatment and prevention of opportunistic illnesses, chronic conditions and complications that occur in HIV-infected persons who now tend to live longer because of benefits of HAART.

In light of these needs, the CDC has been supporting, since 1993, the HIV Outpatient Study (HOPS), a study of standardized and secure medical chart abstractions from HIV-infected patients receiving routine HIV-related outpatient care.

The data abstracted from HOPS clinics are one of the largest and most comprehensive set of information of its kind in the United States (over 10,000 patients seen to date), providing uniquely valuable insights regarding the treatment and prevention of HIV infection in Americans. The CDC intends to continue this data abstraction activity at the HOPS sites, which will enable CDC to carry out a central component of its public health mission, namely, gathering and analyzing data to develop guidelines and recommendations for clinicians, public health departments, and other partners participating in the prevention and treatment of HIV/AIDS.

Among the existing contemporary HIV cohorts, which contribute data to the North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD) (reviewed by Gange, 2007, and listed at http://statepiaps.jhsph.edu/naaccord/Cohorts/index.html), few studies prospectively tracked large numbers of patients as diverse

in their geography, race, gender, HIV risk group, and social and economic class as the HOPS.

The HOPS allows for: the examination of trends in the epidemiology of chronic HIV disease in this aging U.S. cohort; the identification of interactions between HIV disease, antiretroviral therapy, and other comorbidities; the characterization of the optimal management strategies for HIV-infected patients to reduce morbidity and mortality (e.g., data on drug toxicities, effectiveness of clinical interventions); and monitoring of sexual and drug use behaviors of HIV-infected patients to inform risk-reduction programs. The HOPS collects self-reported data on HIV-positive patients' risk behaviors (including sexual, drug use, tobacco use) which can be linked to diagnoses, treatments and laboratory findings, and inform secondary HIV prevention.

HOPS data can be used to monitor the progress in achieving the goals of the National HIV/AIDS Strategy (White House, 2010): to increase retention in HIV care, to reduce racial/ethnic disparities in treatment outcomes, and to reduce secondary HIV transmission.

2. Purpose and Use of the Information Collected

The HIV Outpatient Study (HOPS) relies on data already collected in the existing electronic charting systems at participating clinics, and combines and harmonizes these data in a centralized application, in order to obtain complete record of prospective outpatient visits to leading HIV clinicians, made by patients diverse in their geography, race, gender, HIV risk group, and social and economic class. Cerner Corporation currently collects these data at nine CDC funded outpatient HIV clinics in Tampa, FL; Washington, DC; Stony Brook, NY; Chicago, IL; Denver, CO; Philadelphia, PA. The data are supplemented with information on patients' sociodemographic characteristics and risk behaviors collected using a brief Telephone Audio-Computer Assisted Self-Interviewing (T-ACASI) survey or an identical web-based Audio-Computer Assisted Self-Interviewing (ACASI) (**attachments 3a, 3b and 5**).

The objectives of the HOPS are to: (1) Describe and monitor trends in demographics, symptoms, diagnosis, treatments, and disease outcomes in a population of HIV-positive outpatients in clinics across the United States, (2) Describe factors associated with

clinical, immunologic and virologic successes, as well as improved survival, (3) Characterize (new) problems associated with long-term HIV infection and its treatment and (4) Describe HIV risk behaviors and other risk behaviors (e.g., tobacco use, adherence to antiretroviral therapy) among HIV-infected patients. Four hundred–fifty new HOPS study participants are to be recruited annually into the HOPS from a pool of HIV-infected individuals currently in HIV-care at the nine aforementioned clinics. Patients are approached by HOPS project clinic staff during one of their routine clinic visits and invited to participate in the HOPS. Patients, who have been actively recruited throughout the study period for this ongoing project, sign informed consents to have information collected from their physician visits, aggregated and analyzed by the CDC's Contractor (CERNER Corporation), and reported without any personal identifiers to the CDC. (**Attachment 4**). The HOPS protocol states that all patients are to be approached once per year by HOPS project clinic staff and offered behavioral survey (**Attachment 3a, 3b and 5)**. We estimate 2,500 patients will participate in an annual voluntary behavioral survey.

To ensure that the sample of patients from each site is representative of that site, practitioners are asked to attempt to enroll at least 80% of clinic patients, with a minimum participation of 75 active practice patients. Due to human resource constraints at some large HIV clinic sites, which have 300 or more patients actively participating, enrollment is focused on those patients who are newly entering HIV care at the participating HOPS clinics. HOPS is a convenience sample of patients in care at the participating HIV clinic sites.

3. Use of Improved Information Technology and Burden Reduction

Abstracted medical record data will be entered into password protected and encrypted software application via laptop or desktop computer. Behavioral survey data will be collected via telephone computer assisted survey application or a web-based computer assisted survey application. HOPS patients accessing the telephone administered behavioral survey are assigned unique 4-digit numbers, and asked to complete the anonymous survey by dialing a 1-800 number from a private location in the clinic or from home (**attachments 3a, 3b and 5**). Those patients completing the web-based behavioral survey are given a unique code and asked to complete the anonymous survey

located on a secure encrypted web site from a private location in the clinic or from home. The ACASI will employ industry standard secure protocol for on-line data transmission encryption and no patient identifiable information is collected or stored. 100% of medical abstractions and behavioral surveys will be collected using electronic applications.

4. Efforts to Identify Duplication and Use of Similar Information

We reviewed currently funded programs and did not identify potential areas of duplication. We are not aware of any department or agency that collects prospective longitudinal data on clinical outcomes and related behaviors from a comparably large and demographically diverse population of both HIV-infected men and women in care.

5. Impact on Small Businesses or Other Small Entities

No small business will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

Clinical data abstraction activities performed by paid HOPS study staff cover a continuous record of all outpatient clinic visits and hospital discharge records from the time of HOPS enrollment. Such continuous longitudinal medical abstraction is essential to permit analyses and understanding of the epidemiologic relationships between treatments, laboratory values and diagnoses among HIV-infected patients followed in the HOPS. Behavioral survey data are collected from HIV-infected patients annually. Collecting data less than annually would not be advantageous, nor would it meet the needs of the HOPS study clinics that rely on the consistent collection of relevant data to augment the clinical care of their HIV-infected patient population. CDC needs to monitor HIV risk behaviors annually in order to inform Prevention with Positives programming which includes reducing new HIV infections, increasing knowledge of HIV infection status and increasing linkage to prevention, care and treatment services. HOPS clinics also use these behavioral survey results for tailoring their prevention activities to types of patients most at risk of unhealthy behaviors and poor clinical outcomes.

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

This request fully complies with regulation 5 CRF 1320.5.

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

A 60-day federal register notice to solicit public comments was published on 01/06/2015, Volume 80, Number 3, page number 506-507. A copy of this publication is attached **(Attachment 2).** No public comments were received.

Several consultations were conducted with various scientists and public health practitioners outside the agency.

In preparation for this new data collection activity, monthly consultation calls were held with HOPS data analysts, and a statistical consultant to discuss analytic and data collection considerations in the HOPS project. Bimonthly calls were also held with medical doctors specializing in the treatment of HIV associated with the project to discuss which data to gather for HIV-infected patients - including which diagnoses, laboratory measurements and treatments - so as to best inform epidemiologic analyses for patient management and care. HOPS data have been routinely presented at international HIV conferences (including Conference on Retroviruses and Opportunistic Infections and International AIDS Society Meeting) where the project benefits from scientific peer review and consultations for continuous quality improvement.

Consultant	**Organization**	**email**
Joan Chmiel, PhD Statistician	Northwestern University School of Medicine, 645 N. Michigan Ave, Suite 900; Chicago, IL 60611	jchmiel@northwestern.edu
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Benjamin Young, MD, PhD Sr. Vice President/Chief Medical Officer	International Association of Providers of AIDS Care. 1990 M Street, NW Suite 380 Washington, DC 20036	benjaminyoungmd@gmail.com
Ellen Tedaldi, MD Medical doctor	Temple University, 1316 W, Ontario Street; Jones Hall, Suite 808; Philadelphia, PA 19140	ellen.tedaldi@tuhs.temple.edu
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MD Medical epidemiologist	University School of Public Health, 950 New Hampshire Ave, NW 7th Floor Washington, DC 20052	
Harlen Hayes, MPH, Statistician	Quantitative Research and Biostatistics. CERNER Corporation, 1953 Gallows Rd, Suite 500; Vienna, VA 22180	harlen.hays@cerner.com

9. Explanation of Any Payment or Gift to Respondents

This data collection activity does not offer payments, incentives, or tokens of appreciation to respondents.

10. Assurance of Confidentiality Provided to Respondents

The HOPS does not have the CDC's Certificate of Confidentiality. However, the HOPS has multiple levels of protection to ensure privacy and security of the information collected from HOPS participants. The information abstracted from medical charts is encrypted in the HOPS data collection database. Only local HOPS clinic staff has access to the participants' personal identifying information. The privacy act does not apply to this activity. The de-identified, but sensitive information from medical records and optional patient survey are transferred to the CDC via secure ftp site for analyses. The CDC receives all patient information labelled with a unique HOPS participant ID only. The data collection database maintained by the CDC Contractor has received Data Security Certification and Accreditation from the CDC Information Technology Office.

IRB Approval

The HIV Outpatient Study (HOPS), protocol 1997 has been reviewed and approved by the CDC IRB (**Attachment 7**).

10.1 Privacy Impact Assessment

a. An overview of the data collection system

HOPS data are collected by medical chart abstraction (**attachment 6**). Additional behavioral survey data are collected via a self-

administered telephone or web-based survey in a private setting within the HOPS clinic site or at home. The Contractor transfers the de-identified medical record abstraction and the behavioral survey data to the CDC via secure ftp site.

b. A description of the information to be collected

The HOPS contractor abstracts participants' medical records for data on demographics, risk factors, HIV disease history as well as diagnoses, treatments and labs collected at each medical encounter. An optional 7-minute telephone/web-based assessment gathers supplemental data on patient's risk behaviors and demographics that are directly relevant to their HIV care (**Attachment 3a, 3b and 5)**.

c. A description of how the information will be shared and for what purpose

CDC will disseminate research study findings through national and international conference presentations, and the study findings will be also published in peer-reviewed medical and public health related journals. The patients give voluntary informed consent to participate in this research study. In all publications and presentations, data from patients are presented in aggregate without any personally identifying information. This sharing of information allows HOPS to contribute to the body of medical and public health knowledge to optimize patient management and HIV/AIDS prevention. The HOPS findings have been used to support recommendation in Dept. of Health & Human Services (DHHS) HIV treatment guidelines and Prevention and Treatment of Opportunistic Illnesses guidelines. The HOPS study has published several papers that inform on the progress in achieving the goals of the National HIV/AIDS Strategy (White House, 2010): to increase retention in HIV care, to reduce racial/ethnic disparities in treatment outcomes, and to reduce secondary HIV transmission

d. A statement detailing the impact the proposed collection will have on the respondent's privacy

The HOPS has multiple levels of protection to ensure privacy and security of the information collected from HOPS participants. The information abstracted from medical charts is maintained encrypted in the HOPS data collection database. Only local HOPS clinic staff has access to the participants' personal identifying information.

The de-identified but sensitive information from medical records and optional patient survey are transferred to the CDC via secure ftp site for analyses. The CDC receives all patient information labelled with a unique HOPS participant ID only. The data collection database maintained by the CDC Contractor has received Data Security Certification and Accreditation from the CDC Information Technology Office.

e. Whether individuals are informed that providing the information is voluntary or mandatory

HOPS patients are informed and able to participate only after reviewing and signing an informed consent form that states that their participation in the study is voluntary and they may refuse to participate or quit at any time (**Attachment 4**)

f. Opportunities to consent, if any, to sharing and submission of information

When patients are asked to take part in the HOPS study, they are provided a consent form in which they are notified the study wishes to gather information from their medical records and subsequent optional surveys and that if data from this study will be published in medical journals or presented at conferences this information will not contain any personal identifying information (**attachment 4**)

g. How the information will be secured?

The personally-identifiable information (which may include patient's name, address, phone number, medical record number and social security number) are entered into the HOPS web-based data collection database at the local HIV clinic sites are kept encrypted in that database. The database was developed by the CDC contractor for the HOPS project. The designated Contractor staff extracts de-identified data entered by each of the local sites for centralized data quality control processing and analyses. The CDC receives all patient information labelled with a unique HOPS participant ID only. The data collection database maintained by the CDC Contractor has received Data Security Certification and Accreditation from the CDC Information Technology Office.

Additionally, HOPS participants are asked to complete a brief survey once per year. HOPS participants who elect to complete the survey

are asked questions related to their HIV care: use of alcohol and drugs, cigarette smoking, adherence to HIV medications, sexual activity and disclosure of HIV status to partners. They complete the assessment by dialing a 1-800 number (T-ACASI) or via a secure encrypted website (W-ACASI) from a private location in the clinic or home. The HOPS Contractor and the CDC access these data without any personal identifiers and labelled with HOPS participant ID only. Only aggregate survey results are shared with the HOPS clinic staff.

HOPS patient informed consent forms with patient name and signature are kept in locked file cabinets in locked HIV clinic offices (two levels of protection) or scanned as an attachment to patient medical record and kept electronically under password protection. HOPS project staff at the local HIV clinic are the only persons who have access to these consent forms, except that Contractor's designated staff may view these consents during site audits.

h. Whether a system of records is being created under the Privacy Act

The designated Contractor staff extracts de-identified medical record data entered by each of the local sites for centralized data quality control processing and analyses. Additionally, the HOPS contractor receives completed telephone and web-based survey data via secure encrypted data transfer. The HOPS Contractor and the CDC receive these data without any personal identifiers and labelled with HOPS participant ID only. All HOPS data are stored at the CDC on a secure network in folders with access restricted to HOPS project officers and data managers.

11. Justification for Sensitive Questions

HIV can be transmitted from person to person through sexual contact and the sharing of HIV contaminated needles and syringes. Understanding epidemiology of HIV infection necessitates the behavioral survey collecting sensitive data regarding disclosure of HIV/AIDS status, medical history, sexual orientation, sexual practices, and alcohol and drug use. In addition, demographic data including race/ethnicity and drug use history are abstracted from medical records. Although the behavioral and demographic information requested is sensitive, it is routinely collected as part of the clinical care activities for the HIV-infected patients seen in HOPS clinics. Additionally, the objectives of HOPS and its goal to inform

the National HIV/AIDS strategy cannot be accomplished without the collection of this information. Collection of these data will be used to understand what may impact HIV care and treatment and how these behaviors and other health conditions may affect the clinical course of HIV disease, for example, how alcohol or drug use might affect adherence to antiretroviral medication and lead to higher HIV viral load. These data will also be used to enhance HIV prevention programs designed to reduce high-risk behaviors in persons most likely to transmit HIV.

The context in which questions are asked helps to overcome their potential sensitivity. There are several steps taken in HOPS to minimize sensitivity and reiterate to the respondent the legitimate need for the information:

Nearly all questions allow for responses of “don’t know” or “refuse to answer.”

Consent scripts make it clear that the survey is sponsored by CDC and the local participating clinic and that the information will be put to important uses (**attachment 4**).

Toll-free phone numbers are provided if the respondent has questions about the survey.

The questionnaire is carefully organized to lead smoothly from one topic to another. Transitions are made clear to respondents and the need for the information explained. Assurances about the privacy of the data are reiterated.

12. Estimates of Annualized Burden Hours and Costs

HOPS participants are offered the opportunity to participate in an optional annual behavioral survey (**attachments 3a and 3b**). Those who elect to participate are asked questions related to their HIV care: use of alcohol and drugs, cigarette smoking, adherence to HIV medications, sexual activity and disclosure of HIV status to partners. Among the estimated 2,500 HOPS patients participating in the HOPS in any given year, all will be invited by HOPS project clinic staff to participate in an annual voluntary 7-minute behavioral assessment. Patients will complete the brief assessment by dialing a 1-800 number (T-ACASI) or via a secure encrypted

website (W-ACASI) from a private location in the clinic or home. The average annual burden to HOPS participants completing telephone/web-based behavioral assessments is 7 minutes. HOPS medical chart abstraction is carried out by paid HOPS study staff and requires no patient contact and therefore places no burden on the HOPS patients. We estimate consenting 450 new participants per year across all HOPS study sites (50 participants for each of 9 sites). The consent process takes approximately 15 minutes to complete.

A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
HOPS Study Patients	Behavioral Survey (att 3)	2,500	1	7/60	292
HOPS Study Patients	Consent form (att 4)	450	1	15/60	113
Total					405

Type of Respondent	Form Name	Total Burden Hours	Hourly wage rate	Total respondent costs
HOPS study Patients	Behavioral survey (att 3)	292	$15.22	$4,444.24
HOPS Study Patients	Consent form (att 4)	113	$15.22	$1,719.86
Total				$6,164.10

B. Estimated Annualized Cost to Respondents

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

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

14. Annualized Cost to the Federal Government

The annualized cost to the government is $2,138,478.92. The cost of this project for the three years is estimated to be $2,138,478.92 x 3 years = $6,415,436.76. The hourly rate was determined by using information contained in the job title table (43-4111 Interviewers, Except Eligibility and Loan) obtained from the US Department of Labor, Bureau of Labor Statistics: **http://www.bls.gov/oes/current/oes434111.htm** (April 14, 2014)

Expense Type (Based on FY14 dollars)	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government		
	HOPS personnel	
	Epidemiologist-13 (1) 100%	$97,869
	Epidemiologist-14 (1) 100%	$119,050
	Total direct costs to federal government	**$216,919**
Contractor and Other Expenses*	Contractor(Project Admin, Data Management & Analysis)	$522,645.29
	Supplemental Analytic Support	$90,832.93
	Senior Statistician	$30,758.03
	Site Research Consultants (Data abstraction) – HOPS	$816,528.48
	Principal Investigators	$110,189.51
	Site Sub-investigators	$72,057.92
	Licenses and IT support	121,941.56
	Other (PCs, printers, shipping, internet)	$13,915.96
	Travel	$12,730.00
	Contractor Indirect Labor (accounting)	$14,264.82
	Overhead (senior statistician)	$30,758.03
	Investigator's Meeting	$44,669.13
	Contractor Profit (7.5% of Cerner Labor Costs)	$40,268.26
	Total contractor and other expenses	**$1,921,559.92**

	TOTAL COST TO THE GOVERNMENT	**$2,138,478.92**

*Salary estimates were obtained from the US Office of Personnel Management salary scale EFFECTIVE JANUARY 2015 at http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/15Tables/html/ATL.aspx

The personnel related to the HIV Outpatient Study (HOPS) data collection include project officers (epidemiologists) at the GS-13 and 14 levels. Travel by the contractor is related to providing technical assistance and conducting site visits and audits. Meeting(s) that will be held include the annual local HOPS principal investigators' meeting.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Clearance is requested for 3 years. The following is a brief overview of the HOPS Timeline.

Project Time Schedule	
Activity	**Time Schedule**
Year 1	
Approach and consent patients	Starting 3-6 months after OMB approval and for the rest of fiscal year
Abstract medical records of interviewed patients	Starting 3-6 months after OMB approval and for the rest of fiscal year
Data management	Starting 3-6 months after OMB approval and for the rest of fiscal year
Analysis	6-12 months after OMB approval and for the rest of the fiscal year
Publication	12 months after OMB approval
Year 2	
Approach and consent patients	Continuation from year 1: 13-18 months after OMB approval and continuing through the fiscal year.
Abstract medical records of	Continuation from year

interviewed patients	1: 13-18 months after OMB approval and continuing through the fiscal year.
Data management	Continuation from year 1: 13-18 months after OMB approval and continuing through the fiscal year.
Analysis	Continuation from year 1: 18-24 months after OMB approval and continuing through the fiscal year.
Publication	Continuation from year 1: 24 months after OMB approval and continuing through the fiscal year.
Year 3	
Approach and consent patients	Continuation from year 2: 25-30 months after OMB approval and continuing through the fiscal year.
Abstract medical records of interviewed patients	Continuation from year 2: 25-30 months after OMB approval and continuing through the fiscal year.
Data management	Continuation from year 2: 25-30 months after OMB approval and continuing through the fiscal year.
Analysis	Continuation from year 2: 33-36 months after OMB approval and continuing through the fiscal year.
Publication	Continuation from year 2: 36 months after OMB approval and continuing through the fiscal year.

17. Reasons(s) Display of OMB Expiration Data is Inappropriate

The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.

REFERENCES

Zuniga,José M., Whiteside,Alan, Ghaziani, Amin, and Bartlett, John G. (2009, September). A Decade of HAART: The Development and Global Impact of Highly Active Antiretroviral Therapy. Oxford Scholarship Online: DOI: 10.1093/acprof:oso/9780199225859.001.0001