HIV Outpatient Study (HOPS)

OMB No. 0920-1080
EXTENSION

Supporting Statement A

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Table of Contents

Section

EXHIBITS

Attachments

9. Privacy Impact Assessment

• Goal of the study: 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: 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 (Centers for Disease Control and Prevention).

• Methods to be used to collect: 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: The HOPS study population is a demographically diverse cohort of HIV-infected adult outpatients seen at 8 well-established public and private HIV clinics in the United States.

• How data will be analyzed: The data will be analyzed by a variety of methods most appropriate for the research questions and variables collected (primarily longitudinal analyses, adjusting for potential confounders, see HOPS publications record). Statistical analyses will include simple descriptive statistics, linear regression, logistic regression, survival analyses, and repeated measures analyses.

• Impact of COVID -19 Pandemic: During COVID-19, HIV Outpatient Study data collection continued with some modifications. The HOPS clinics and/or their institutions determined the guidelines for their routine HIV patient care. In accordance with state, local and institutional/site/IRB specific guidance regarding COVID-19 related public health safety measures, sites employed some or all of the following:

(1) limited in-person patient interactions by conducting routine patient visits via telephone, telemedicine or other virtual technologies; (2) temporarily suspended all study recruitment, enrollment and consents; (3) either (a) temporarily suspended or (b)limited data entry maintenance based on revised patient interactions.

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 extension for a previously approved data collection called “HIV Outpatient Study (HOPS)” (OMB No. 0920-1080, exp. 09/30/2021).

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.

The HIV Outpatient Study (HOPS) is a longitudinal observational study of ambulatory patients in care at eight HIV outpatient clinics in six cities: Tampa, FL; Washington, DC; Stony Brook, NY; Chicago, IL; Denver, CO; and Philadelphia, PA. 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), HOPS is one of few that prospectively track a large number of patients so

diverse in their geography, race and ethnicity, gender, HIV risk group, and mix of public and private payors/insurance coverage.

The 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 a complete record of prospective outpatient visits to leading HIV clinicians. Medical chart information is abstracted for HOPS by CDC's contractor, Cerner Corporation. The medical chart data are supplemented with self-reported information on patients' sociodemographic characteristics and risk behaviors collected using a brief annual survey.

The CDC intends to continue the HOPS, 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. No changes to the study design or method are proposed. This information collection is authorized under Section 301(a) of the Public Health Services Act (42.U.S.C.241) (**Attachment 1**).

2. Purpose and Use of the Information Collected

The overall purpose of the HOPS database and study design is to collect information about the demographic characteristics, symptoms, treatments, and laboratory values of a dynamic cohort of ambulatory HIV positive patients seen at eight clinics nationwide. The main objective of the project is to assess the efficacy, durability, and adverse effects of antiretroviral therapy in clinical practice.

Specific aims 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.

The HOPS relies on two sources of information. Medical records are the primary data source. Information abstracted from medical records includes demographics and risk behaviors for HIV infection; symptoms; diagnosed conditions; medications prescribed; all laboratory values, including CD4+ T-lymphocyte (CD4+) cell counts, plasma HIV-RNA determinations, and genotype, phenotype, and trophile results; and data on visit frequency, AIDS, and death (see **Attachment 6** for a summary of items that are abstracted from clinical charts by the research team). HOPS participants are also invited to complete an annual behavioral assessment, which is optional. For convenience, the behavioral survey can be completed via a 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 behavioral assessment collects information from patients 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.

During the previous 3-year period, milestones and accomplishments of the HOPS data collection activity included the detection and reporting on significant new epidemiologic findings in chronic HIV disease, associated coinfections (e.g., viral hepatitis, sexually transmitted infections) and non-AIDS comorbidities (e.g., cardiovascular disease, diabetes, and cancer), and characterizing optimal screening, management, and treatment strategies for persons living with HIV. A list of publications is provided in **Attachment 8**. The publications address multiple domains in HIV infection and treatment that deepen the understanding of HIV epidemiology among patients in HIV care, and relate to the goals of the National HIV/AIDS Strategy.

Over the years, findings from the HOPS have been repeatedly cited in the Department of Health and Human Services Guidelines on “Use of Antiretroviral Agents in Adults and Adolescents Living with HIV” (https://clinicalinfo.hiv.gov/guidelines). The published results have been used by the CDC and its public health and clinical partners for (i) optimizing care for the prevention of HIV-related disease in adults and for prevention of ongoing HIV transmission, (ii) for increasing access to care and improving health outcomes for

people living with HIV, and (ii) for reducing HIV-related disparities and health inequities.

Onwards, the HOPS data can be used to inform on the progress toward achieving the goals of the White House's Ending the Epidemic Initiative, that depend on improving HIV treatment and retention in HIV care, reducing racial/ethnic disparities in morbidity and mortality, and limiting secondary HIV transmission and thus new HIV infections in the U.S. population.

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. One hundred percent 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

This data collection will not involve small businesses.

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 was published on 09/14/2020, Volume 85, Number 178, page number 56616-56618. A copy of the Notice 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**
Rick Novak, MD Medical doctor	University of Illinois College of Medicine at Chicago, 808 S Wood St, Chicago, IL 60612	rmnovak@uic.edu
Frank Palella, MD Medical doctor	Northwestern University School of Medicine, 645 N. Michigan Ave, Suite 900; Chicago, IL 60611	f-palella@northwestern.edu
Jonathan Mahnken, PhD Statistician	The University of Kansas Alzheimer's Disease Center, 3901 Rainbow Blvd. Kansas City, KS 66160	jmahnken@kumc.edu
Ellen Tedaldi, MD Medical doctor	Temple University, 1316 W, Ontario Street; Jones Hall, Suite 808; Philadelphia, PA 19140	ellen.tedaldi@tuhs.temple.edu
Alan Greenberg, MD Medical epidemiologist	George Washington University School of Public Health, 950 New Hampshire Ave, NW 7th Floor Washington, DC 20052	aeg1@gwu.edu
Jeff Naughton, MBA, Market General Manager	CERNER corporation 2800 Rockcreek PKWY; Kansas City, MO 64117-2521.	Jeff.Naughton@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 CDC/ATSDR Privacy Officer assessed this package for applicability of 5 U.S.C. § 552a and determined that the Privacy Act applies to the overall information collection. The applicable System of Records Notice is •09-20-0160 "Records of Subjects in Health Promotion and Education Studies". The NCHHSTP IT Security Information System Security Officer (ISSO) consulted on the system

security described in this project. The data system for this collection resides at an external third party data center and underwent a Privacy Impact Assessment (PIA) (see **Attachment 9**) when it was granted authority to operate during the SA&A process (Enterprise Systems Catalog, IT Record ID: 2327).

Personally-identifiable information (PII), which may include patient's name, address, phone number, medical record number, are entered into the HOPS web-based data collection database at the local HIV clinic sites and kept encrypted in that database. This information is collected by the clinics as part of routine patient care and is not collected on behalf of CDC. The Behavioral Survey Instrument (**Attachment 3a**) does not collect this PII. The PII is collected as a result of the Data Abstract process (**Attachment 6**) but it is kept encrypted and is never transmitted to the CDC. The PII primary purpose is to monitor trends in the demographics, symptoms, diagnoses, and treatments in a population of HIV-infected outpatient clinics across the United States. The designated HOPS Contractor staff extracts de-identified data entered by each of the local sites for centralized data quality control processing and analyses. CDC receives no PII variables, all patient information is 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.

The HOPS does not have a 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. De-identified sensitive information from medical records and optional patient survey are transferred to the CDC via secure ftp site for analyses.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

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

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 (Centers for Disease Control and Prevention) 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 medical chart abstraction is conducted on a continuous basis for all patients enrolled in HOPS. The burden table does not include a line item for this study component as medical chart abstraction is carried out by paid HOPS study staff and requires no patient contact. **Attachment 6** provides a summary of data elements that are obtained from clinical records.

All HOPS participants are offered the opportunity to participate in an optional annual behavioral survey (**attachments 3a and 3b**). Among the estimated 2,700 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.

We estimate consenting up to 450 new participants per year across all HOPS study sites (50-60 participants for each of 8 sites). The consent process takes approximately 15 minutes. Because not all participants will answer all 12 of the new items, we are not anticipating an increase in burden time.

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 3a,b)	2,700	1	7/60	315
HOPS Study Patients	Consent form (att 4)	450	1	15/60	113
Total					428

B. Estimated Annualized Cost to Respondents

The annualized burden cost is estimated in table A12b below. The annualized burden cost is $11,008.16. Hourly wages for the four respondent categories were determined as follows:

The mean hourly wage for patients was estimated at a rate of 25.72, which is the mean hourly wage reported on the 2016 Bureau of Labor Statistics, National Occupational Employment and Wage Estimates across all occupations in the United States (accessed on May 21, 2020 at https://www.bls.gov/oes/current/oes_nat.htm).

Type of Respondent	Form Name	Total Burden Hours	Hourly wage rate	Total respondent costs
HOPS study Patients	Behavioral survey (att 3a,b)	315	$25.72	$8,101.80
HOPS Study Patients	Consent form (att 4)	113	$25.72	$2,906.36
Total				$11,008.16

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 **$2,281,603.33**. The cost of this project (contract# 75D30120C08752) for the three years is estimated to be $2,281,603.33 x 3 years = $6,844,809.99. 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** (May 2019)(accessed on May 21,2020)

Expense Type (Based on FY14	Expense Explanation	Annual Costs (dollars)

dollars)		
Direct Costs to the Federal Government		
	HOPS personnel	
	Epidemiologist-13 (1) 100%	$118,547
	Epidemiologist-14 (1) 100%	$140,081
	Total direct costs to federal government	**$258,628**
Contractor and Other Expenses*	Contractor(Project Admin, Data Management & Analysis)	$550,229.28
	Supplemental Analytic Support	$95,626.88
	Senior Statistician	$32,381.37
	Site Research Consultants (Data abstraction) – HOPS	$859,622.93
	Principal Investigators	$116,005.05
	Site Sub-investigators	$75,860.97
	Licenses and IT support	$128,377.35
	Other (PCs, printers, shipping, internet)	$14,650.41
	Travel	$13,401.86
	Contractor Indirect Labor (accounting)	$15,017.68
	Overhead (senior statistician)	$32,381.37
	Investigator's Meeting	$47,026.66
	Contractor Profit (7.5% of Cerner Labor Costs)	$ 42,393.52
	Total contractor and other expenses	**$2,022,975.33**
	TOTAL COST TO THE GOVERNMENT	**$2,281,603.33**

*Salary estimates were obtained from the US Office of Personnel Management salary scale EFFECTIVE JANUARY 2020 at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2020/ATL.pdf. (accessed on May 21,2020)

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 request for extension of the approved collection. In the previous approval period, the burden for the annual behavioral assessment was based on the estimated participation of 2,500 respondents. This was an empirical estimate of likely participation. In the current request, the burden for the annual behavioral assessment is estimated on the basis of 2,700 respondents (i.e., the total size of the HOPS cohort). CDC revised this estimate to ensure that the HOPS clearance provides capacity for the maximum number of respondents. This change adds 23 burden hours to the previous estimate. There are no changes to information collection content or methods.

16. Plans for Tabulation and Publication and Project Time Schedule

Clearance is requested for 3 years beginning 09/2021. 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.