

Supporting Statement A

OMB control # 0920-0775

*Formative Research to Develop Social Marketing Campaigns-
Routine HIV Testing for Emergency Medicine Physicians,
Prevention Is Care, and Partner Services*

March 1, 2011

PROJECT OFFICER:
Donata R. Green, Ph.D.
Centers for Disease Control and Prevention
Division of HIV/AIDS Prevention
8 Corporate Blvd.
Mail Stop E-49, Room 5020
Atlanta, GA 30329
(404) 639-3869 office
(404) 639-2007 fax
dqg7@cdc.gov

TABLE OF CONTENTS

Section

- A. Justification.
 - 1. Circumstances Making the Collection of Information Necessary
 - 2. Purpose and Use of the Information Collection
 - 3. Use of Improved Information Technology and Burden Reduction
 - 4. Efforts to Identify Duplication and Use of Similar Information
 - 5. Impact on Small Businesses or Other Small Entities
 - 6. Consequences of Collecting the Information Less Frequently
 - 7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
 - 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
 - 9. Explanation of Any Payment or Gift to Respondents
 - 10. Assurance of Confidentiality Provided to Respondents
 - 11. Justification for Sensitive Questions
 - 12. Estimates of Annualized Burden Hours and Costs
 - 13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers
 - 14. Annualized Cost to the Government

15. Explanation for Program Changes or Adjustments
16. Plans for Tabulation and Publication and Project Time Schedule
17. Reason(s) Display of OMB Expiration Date is Inappropriate
18. Exceptions to Certification for Paperwork Reduction Act Submissions

B. Collection of Information Involving Statistical Methods

1. Respondent Universe and Sampling Methods
2. Procedures for the Collection of Information
3. Methods to Maximize Response Rates and Deal with Nonresponse
4. Test of Procedures or Methods to Be Undertaken
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

References

EXHIBITS

- Exhibit 8.1 Individuals Consulted During the Development of Routine HIV Testing Campaign
- Exhibit 8.2 Individuals Consulted During the Development of the PIC Campaign
- Exhibit 12.1 Estimated Annualized Burden Hours
- Exhibit 12.2 Estimated Annualized Burden Costs
- Exhibit 14.1 Estimated Cost to the Government
- Exhibit 16.1 Project Time Schedule

LIST OF ATTACHMENTS

1. Authorizing Legislation and Other Relevant Laws
- 2(a). Data Collection Instruments – Routine HIV Testing in
Emergency Departments
- 2(b). Data Collection Instruments – Prevention is Care
(PIC)
- 2(c). Data Collection Instruments – HIV Partner Services
(Concept Testing)
- 2(d). Data Collection Instruments – HIV Partner Services
(Materials Testing)
- 3(a). Federal Register Notices to the Public (30-day)
- 3(b). Federal *Register* Notices to the Public (60-day)
4. Institutional Review Board (IRB) Approval
- 5(a). Consent Forms – Routine HIV Testing in Emergency
Departments
- 5(b). Consent Forms – Prevention is Care (PIC)
- 5(c). Consent Forms – HIV Partner Services
- 6(a). Study Screening Instruments – Routine HIV Testing in
Emergency Departments
- 6(b). Study Screening Instruments – Prevention is Care
(PIC)
- 6(c). Study Screening Instruments – HIV Partner Services
- 7(a). Paper and Pencil Survey – Routine HIV Testing in
Emergency Departments
- 7(b). Paper and Pencil Survey – Prevention is Care (PIC)
- 7(c). Paper and Pencil Survey – HIV Partner Services
8. Privacy Agreement

Formative Research to Develop Social Marketing Campaigns- Routine HIV Testing for Emergency Medicine Physicians, Prevention Is Care, and Partner Services

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), Division of HIV/AIDS Prevention, requests a time extension for OMB 0920-0775 to continue a formative research study to support CDC's efforts in further developing three social marketing campaigns targeting infectious disease specialists, primary care physicians, and emergency department physicians. The campaigns of focus remain the same: Routine HIV Testing, Prevention is Care (*PIC*) and Partner Services. To date, we have conducted a total of 162 interviews and have 82 remaining interviews to conduct. All exploratory research has been completed. The remaining interviews will be to finish creating materials for the three campaigns. The remaining interviews from 0920-0775 were not conducted due to budget reductions and eliminations. Therefore all materials were not developed. The materials to be tested will supplement the existing materials developed from the 162 interviews and will contain updated surveillance data, continue to promote CDC's 2006 *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care*

Settings among physicians in private practice and emergency departments and promote the new recommendations, if released in time. These materials will be used by the target audience to assist them with offering and conducting HIV prevention and testing. The remaining interviews are necessary to finish creating all of the materials and ensure the new materials are appropriate for the target audience.

Historically, prevention efforts have targeted people at risk for HIV infection with the goal of keeping those who are HIV negative from becoming infected. However, the epidemic has changed with the introduction of highly active anti-retroviral therapy. Despite advances in treatment and numerous prevention efforts, HIV continues to spread with an estimated 56,000 new HIV infections annually (Hall et al., 2008). An estimated 1.1 million Americans are living with HIV, and 1 out of 5 people with HIV do not know they have it (CDC, 2008). CDC's goal, since 2001, has been to reduce the number of new HIV infections in the United States from an estimated 56,000 to 20,000 per year, focusing particularly on eliminating racial and ethnic disparities in new HIV infections.

Healthy People 2010 and 2020 objectives focus on preventing HIV infection and its related illness and death.

In particular, Healthy People 2010 aimed to reduce the number of new cases of HIV/AIDS diagnosed among adult and adolescents and to increase the proportion of HIV-infected persons who know they are infected. Healthy People 2020 includes these objectives, as well as a new objective aiming to increase the proportion of adults and adolescents who have been tested for HIV in the past 12 months.

In 2010, the Office of National AIDS Policy out of the White House developed the *National HIV/AIDS Strategy (NHAS)* with three primary goals: 1) reducing the number of people who become infected with HIV; 2) increasing access to care and improving health outcomes for people living with HIV; and, 3) reducing HIV-related health disparities. In support of Healthy People 2010 and 2020 and the NHAS, CDC will finish developing all materials for the three campaigns targeting health care providers:

- **Routine HIV Testing:** The goal of this campaign is to increase HIV testing rates among those seeking emergency care services and those who may use emergency services to deliver their primary medical care needs. Those with a lower socioeconomic status (SES) are less likely to receive preventive care from primary care physicians (PCPs) or other health care providers outside emergency department

settings, thus missing the opportunity for routine HIV screening. Research has found that persons with a lower SES often attend emergency departments for primary health care services (Alpert et al. 1996). Therefore, an emergency medicine physician has a unique opportunity to provide HIV screening services that a patient would otherwise not receive, or to counsel a patient to seek HIV testing.

- ***Prevention Is Care (PIC)***: *PIC* seeks to encourage Infectious Disease Specialists (IDS) and Primary Care Providers (PCPs) to screen their patients living with HIV for potential HIV transmission behaviors and deliver brief messages on the importance of protecting themselves and others by reducing their risky behaviors. Therefore, the goal of this campaign is to establish *PIC* as the standard of care for persons living with HIV.
- **Partner Services**: The goal of this campaign is to incorporate Partner Services into the care for persons diagnosed with HIV. Partner Services are a set of activities led by State Health Departments, and supported by healthcare providers, to notify the sex and drug-injection partners of HIV-positive

persons that they have been exposed to HIV; offer them counseling, testing and referral services; and ensure that all HIV-positive persons are linked to appropriate medical care.

The following section of the U.S. Federal Code (see **Attachment 1**) is relevant to this data collection: 42 USC 241, Section 301 of the Public Health Service Act authorizes conduct of “research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man.”

2. Purpose and Use of the Information Collection

The purpose of this study is to continue one time semi structured in person in-depth interviews to finish developing all of the materials for the three social marketing campaigns (Routine HIV Testing, *PIC*, and Partner Services). RTI International, the evaluation contractor, will conduct the interviews and will interview each physician only once in order to finish developing all new campaign materials. We will continue to gain an understanding and identify physicians’:

- Current practices (e.g., HIV testing, behavioral screening, partner notification and referral)
- Use of HIV prevention and education materials with patients
- Perceived and actual barriers to implementing new guidelines/recommendations
- Initial reactions to campaign materials (e.g., visual appeal, format, design, content, usefulness, credibility)
- Preferred channels for obtaining new information on guidelines or practices
- Interest in provider resources and patient educational materials

The three social marketing campaigns will continue to increase the adoption of CDC's 2006 *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings* among physicians in private practice and emergency departments and the new recommendations, if released in time. All data collection instruments will remain the same, see **Attachment 2** for the data collection instruments. We will disseminate the final

study results to the public once all formative research has been completed. The reports will be prepared for and/or by CDC or RTI and will be submitted to peer-reviewed journals where appropriate. All releases of information will be reviewed and approved by CDC.

3. Use of Improved Information Technology and Burden Reduction

The data collection requires that we continue to employ qualitative research methods through the use of one time in person in-depth interviews. The responses from the participants are as important as the interviewers' observation of the participant and the overall interview. Where possible and upon consent from the participant, we will audio tape the interviews to capture all information and assist with preparation of reports.

4. Efforts to Identify Duplication and Use of Similar Information

In order to identify duplication and use of similar information, we conducted a review of the literature to update the existing literature review results. We continued to examine several large periodical journal databases and "gray" literature by exploring the Internet. Searches were performed on several Internet search engines, including

Google, Yahoo, AltaVista, Medline, and Science Direct. We were unable to find duplication or the use of similar information. Therefore, we have confirmed the need to continue developing materials for the present study.

5. Impact on Small Businesses or Other Small Entities

This study does not have impact on small businesses or other small entities. We will schedule all interviews at the convenience of the physician and we will not impact the physicians practice.

6. Consequences of Collecting the Information Less Frequently

This is an ad hoc data collection (i.e., a one-time study to develop three social marketing campaigns and does not require periodic collection of data). There are no legal obstacles to reduce burden. The present study will continue to provide data needed to develop additional materials for the Routine Testing, *PIC*, and Partner Services campaign materials. If we did not conduct this formative research, we would not be able to pre-test the additional campaign materials with the target audiences before they are widely distributed. Our formative research process includes gaining an understanding of a target audience's perceived needs, benefits sought, and barriers

of concern. Subsequently, materials are developed that are responsive to the target audience's perspectives, needs, and concerns. We then test the materials with members of the target audience before they are widely disseminated (Slater, 1995). This project is critically important because it involves testing the additional materials that are being developed as part of the three social marketing campaigns described above.

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

There are no other special circumstances that require the data collection to be conducted in a manner inconsistent with 5 CFR 1320.5 (d)(2). This data collection request fully complies with the regulation.

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

A. A 60-Day *Federal Register* notice for Formative Research to Develop the Routine HIV Testing for Emergency Medicine Physicians, *Prevention Is Care (PIC)*, and Partner Services Social Marketing Campaigns—Extension— (0920-0775, exp. 4/30/2011) was published on December 3, 2010 (Volume 75, Number 232, pages 74574) and solicited comments. No comments were received. A copy of the 30 day

and 60-day *Federal Register* notices can be found as **Attachments 3a and 3b** respectively.

B. The CDC study team collaborated with RTI International staff (evaluation contractor) on the study design, screening instruments, and interview guides. RTI staff is trained and experienced in formative research. CDC recognizes the importance of gaining valuable insights directly from members of the target audience and from organizations and individuals who work with them in the community. Consultation with individuals and related activities occurred for each campaign at various times in 2005 and 2006. Additional consultations occurred in 2010. All individuals consulted are listed below. No major problems were identified that could not be resolved.

At various points in 2005, 2006, 2009 and 2010 we consulted with the following individuals for development of the campaigns' concepts, messages, and materials. Some materials have already been developed based on the 2005 and 2006 consultations and the formative research conducted in those years. In 2009 and 2010 we consulted with additional individuals for continued program direction and development of the remaining materials to be tested under this extension. See Exhibits 8.1 and 8.2 for individuals

consulted by campaign in 2005, 2006, 2009 and 2010. We will continue to consult the individuals listed below as needed.

Exhibit 8.1. Individuals Consulted During the Development of Routine HIV Testing and Campaign

2005-2006 Individuals Consulted	
<p>Bernard M Branson, M.D. Associate Director for Laboratory Diagnostics Divisions of HIV/AIDS Prevention National Center for HIV, STD and TB Prevention Centers for Disease Control and Prevention 1600 Clifton Road Atlanta, GA 30333 (404) 639-6166 BBranson@cdc.gov</p>	<p>Margaret Lampe, RN, MPH Acting Team Lead, EPI Branch Divisions of HIV/AIDS Prevention National Center for HIV, STD and TB Prevention Centers for Disease Control and Prevention 1600 Clifton Road Atlanta, GA 30333 (404) 639-5189 MLampe@cdc.gov</p>
2009-2010 Individuals Consulted	
<p>Amir Qaseem, MD, PhD Senior Medical Associate in the Clinical Program and Quality of Care Department of Medical Education and Publishing Division American College of Physicians 190 North Independence Mall West Philadelphia, PA 19106-1572 215-503-8575 Aqaseem@mail.acponline.org</p>	<p>Celia J. Maxwell, MD, FACP Assistant Vice President for Health Sciences Director of Women's Health Institute Howard University 1315 Leegate Road NW Washington, DC 20012 202-865-7513 cmaxwell@howard.edu</p>
<p>Donna E. Sweet, MD, MACP Professor of Medicine The University of Kansas School of Medicine - Wichita 1010 N. Kansas Wichita, Kansas 67214 316-268-5984 dsweet@kumc.edu</p>	<p>Jeffrey T. Kirchner, DO, AAHIVS Medical Director of Comprehensive Care Center for HIV, Lancaster General Hospital LGH Family & Community Medicine 555 North Duke Street, PO Box 3555 Lancaster, PA 17604 717-544-4940 JTKirchn@LancasterGeneral.org</p>

<p>Jim Sosman, MD Associate Director, HIV Care Program Associate Professor of Medicine, University of Wisconsin School of Medicine and Public Health 2828 Marshall Court, Suite 100 Madison, WI 53705 608-263-5259 Jms@medicine.wisc.edu</p>	<p>Joel Gallant, MD, MPH Associate Director, Johns Hopkins AIDS Service 1830 E. Monument Street Room 443 Baltimore, MD 21205 410-955-7473 jgallant@jhmi.edu</p>
<p>Joseph McGowan, MD, FACP Medical Director, NYS Designated AIDS Center North Shore University Hospital 16 Country Club Lane Briarcliff Manor, NY 10510 516-562-4280 JMcGowan@NSHS.edu</p>	<p>Lynn E. Sullivan, MD Assistant Professor of Medicine, Department of Internal Medicine, Yale University 367 Cedar Street PO Box 208093 New Haven, CT 06520-8093 203-688-9105 lynn.sullivan@yale.edu</p>
<p>Margaret Hoffman-Terry, MD, AAHIVS Chief of HIV Medicine Lehigh Valley Hospital 413 N. Jasper St. Allentown, PA 18109 610-969-2400 mh7c@aol.com</p>	<p>Ron Goldschmidt, MD Director, National HIV/AIDS Clinicians' Consultation Center (NCCC) Professor of Clinical Family and Community Medicine, Vice-Chair, UCSF Department of Family and Community Medicine San Francisco General Hospital 1001 Potrero Avenue, Building 80-83 San Francisco, CA 94110 415-206-5792 rgoldschmidt@nccc.ucsf.edu</p>
<p>Ronald Lubelchek, MD Attending Physician Division of Infectious Diseases John H. Stroger Hospital of Cook County 1372 N. Dean Street, Apt. 1 Chicago, IL 60622 312-864-4590 rlubel@gmail.com</p>	<p>Wilbert Jordan, MD, MPH Medical Director, Oasis Clinic 1807 E. 120th St. Los Angeles, CA 90059 310-668-4213 tojo44@aol.com</p>

Richard Rothman, MD, PhD Johns Hopkins Department of Emergency Medicine 5801 Smith Avenue, Suite 3220 Davis Building Baltimore, MD, 21209 410-735-6428 rrothman@jhmi.edu	Michael S. Lyons, MD, MPH Assistant Professor Department of Emergency Medicine University of Cincinnati College of Medicine 513-558-8629 lyonsme@ucmail.uc.edu
--	--

Exhibit 8.2. Individuals Consulted During the Development of the PIC Campaign

2005-2006 Individuals Consulted	
Bernard M Branson, M.D. Associate Director for Laboratory Diagnostics Divisions of HIV/AIDS Prevention National Center for HIV, STD and TB Prevention Centers for Disease Control and Prevention 1600 Clifton Road Atlanta, GA 30333 (404) 639-6166 BBranson@cdc.gov	Mark Thrun, M.D.—Medical Director, Denver STD/HIV Prevention Training Center 605 Bannock Street, MC 2600 Denver, CO 80204 (303) 436-7071 Mark.Thrun@dhha.org
Judith Absalon, M.D., MPH— Assistant Professor of Epidemiology, Mailman School of Public Health, Columbia University 722 West 168th St, Room 513 New York, NY 10032 (212) 342-0533 ja234@columbia.edu	Howard Grossman, M.D.—Executive Director, American Academy of HIV Medicine 1705 DeSales Street, Suite 700 Washington, DC 20036 (877) 422-4486 howard@aahivm.org
Wayne Bockmon, M.D.—Staff Physician, Montrose Clinic 4706 Westslope Circle Austin, TX 78731 (512) 420-2314 kwb@austin.rr.com	Peter Meacher, M.D.—Medical Director, South Bronx Health Center for Children and Families, Montefiore Medical Center 871 Prospect Avenue Bronx, NY 10459 (718) 991.0605 x 236 pmeacher@montefiore.org

<p>Alwyn Cohall, M.D.—Associate Professor, Harlem Health Promotion Center, Mailman School of Public Health, Columbia University 215 West 125th Street New York, NY 10027 (646) 284-9725 atc1@columbia.edu</p>	<p>Peter Shalit, M.D., Ph.D.—Physician, Swedish Medical Center 1120 Cherry Street, #320 Seattle, WA 98104 (206) 624-0688 psmd@mac.com</p>
<p>Donald T. Evans, M.D.—Physician, Founder, AIDS Project Greater Danbury 115 Mount Pleasant Rd. Newton, CT (203) 426-5626 apgd99@aol.com</p>	
<p>2009-2010 Individuals Consulted</p>	
<p>John Bartlett Chief, Professor of Medicine Division of Infectious Diseases Johns Hopkins University School of Medicine 1830 E. Monument St. RM 439 Baltimore, MD 21205 410.955.7634 jb@jhmi.edu</p>	<p>Constance Benson Professor of Medicine UCSD Antiviral Research Center Department of Medicine Mail Code 8208150 West Washington Street, Suite 100 San Diego, CA 92103 (619) 543-8080 cbenson@ucsd.edu</p>
<p>Wayne Bockmon Practicing Physician Montrose Clinic 4706 Westslope Circle Austin, TX 78731 512.420.2314 (Home) 512.350.6911 (Cell) kwb123@gmail.com</p>	<p>John Brooks Leader, Clinical Epidemiology Team Division of HIV/AIDS Prevention, NCHSTP Centers for Disease Control and Prevention 1600 Clifton Rd., MS E-45 Atlanta, GA 30333 404.639.3894 zud4@cdc.gov</p>

<p>Kevin Charmichael Chief of Service El Rio Special Immunology Associates 1701 W. St. Mary's Road, Suite 160 Tucson, AZ 85745 520.628.8287 kevinc@elrio.org jkcsia@elrio.org</p>	<p>Alwyn Cohall Associate Professor of Clinical Public Health and Clinical Pediatrics Mailman School of Public Health of Columbia University 215 West 125th St., Ground Floor New York, NY 10027 646.284.9725 atc1@columbia.edu</p>
<p>Eric Daar Director of the Division of HIV Medicine Harbor-UCLA Medical Center, Box 400 1000 W. Carson Street Torrence, CA 90509 310.222.2401 edaar@labiomed.org</p>	<p>David Hardy Associate Professor of Medicine Cedars-Sinai Medical Center Infectious Diseases 8700 Beverly Bl, #B-220 Los Angeles, CA 90048 310.423.3896 david.hardy@cshs.org</p>
<p>Peter Meacher Practicing Physician South Bronx Health Center for Children and Families Montefiore Medical Center 871 Prospect Ave. Bronx, NY 10459 718.991.0605 x 236 pmeacher@montefiore.org</p>	<p>Evelyn Quinlivan Assistant Professor of Medicine Director, Infectious Diseases Clinic School of Medicine The University of North Carolina at Chapel Hill Bioinformatics Building 130 Mason Farm Road Campus Box 7030 Chapel Hill, NC 27599 919.966.2536 ebq@med.unc.edu</p>
<p>Peter Shalit Practicing Physician Swedish Medical Center 1120 Cherry Street, #320 Seattle, WA 98104 206.624.0688 psmd@mac.com</p>	<p>Mark Thrun Medical Director, HIV Prevention Denver STD/HIV Prevention Training Center 605 Bannock Street, MC 2600 Denver, CO 80204 303.436.7071 303.602.3645 (NEW) Mark.Thrun@dhha.org</p>

Kimberly Smith Rush University Medical Center 600 S. Paulina Street, Suite 143 Chicago, Illinois, 60612 312-942-5865 Kimberly_Y_Smith@rush.edu	Kathleen E. Squires 1339 Chestnut St. Philadelphia, PA 19107 215-627-0321 Kathleen.Squires@jefferson.edu
---	--

In addition, we will continue to consult with representatives from state health departments on an ongoing basis throughout the campaign development process to ensure that their perspectives are incorporated into the development of the campaign materials.

9. Explanation of Any Payment or Gift to Respondents

We will give all participants a token of our appreciation.

Emergency medicine physician interview	\$200
PCP interview	\$150
IDS interview	\$250

The tokens of appreciation were determined based upon the burden to the participants, taking into account that the participants are physicians, the length of the interview, the fact that participants may have to travel a considerable distance to and from the focus group facility, parking costs, and our previous experience conducting

interviews with PCPs and IDS. This is intended to recognize the time burden placed on the participants, encourage their cooperation, and to convey appreciation for contributing to this important study. Numerous empirical studies have shown that honoraria can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999; Greenbaum, 2000). Physicians are a difficult population to reach because they are highly paid and their time is at a premium. They are frequently bombarded by numerous entities all requesting their time for interviews, surveys and pharmaceutical sales presentations. As a result, they often decline to participate.

Our experience has shown that a smaller token of appreciation does not appear sufficiently attractive to physicians especially given that a higher number of physicians are now paid on a fee-for-service basis, and may be reluctant to leave their office for an interview. For example, if a physician sees a minimum of four patients an hour, each with an average billing rate of \$50, this equates to a physician hourly rate of \$200 without leaving the office. Suggested standard rates range from \$200 to \$250 for physicians (Slaughter, et. al, 1999). This amount is consistent with quotes RTI received in 2006 from focus

group facilities for recruiting PCPs and IDS. Higher amounts may be necessary to recruit physicians who see a higher number of patients per hour or who have additional years of specialized training, such as IDS. We also believe that the token of appreciation will result in higher data validity as physicians become more engaged in the interview process. Participants will receive their token of appreciation immediately after completing their participation in the interview.

10. Assurance of Confidentiality Provided to Respondents

This data collection has received NCHHSTP Project Determination approval as a part of a larger project determination focusing on medical providers. See **Attachment 4**.

In review of this application, it has been determined that the Privacy Act is not applicable.

The contractor RTI will utilize names and addresses to send reminder letters/e-mails and make reminder phone calls, but the information will not be recorded on the actual surveys. All questionable data and the personal identifiers needed to locate potential participants will be stored in separate locked file cabinets in locked offices

in a secured facility. All electronic files will be password controlled and only accessible to fully authorized personnel and maintained and protect to the extent allowed by law.

RTI will select and reserve focus group facilities in each city for each of the three campaigns, overseeing the local focus group facilities' recruitment of participants. Recruitment staff will receive extensive instruction on the importance of maintaining data in a secure manner at all times. Furthermore all employees who work on this study will be required to sign a Privacy Agreement (**Attachment 8**). RTI and the focus group facilities will use screening instruments to identify eligible participants for the study. As participants are recruited, recruitment grids will be prepared to keep track of the recruitment, listing the participants' first name and some demographic obtained from the screener. The recruitment grid will be stored in a locked file cabinet or on a password protected project share drive at RTI, each focus group facility will destroy their copy of the recruitment grid after data collection has been completed. Copies of the recruitment grid will be provided to RTI and CDC for description of the study sample, which will be kept in locked file cabinets or on a

password protected project share drive at RTI and CDC for the duration of the study.

No identifying information will be kept at the focus group facilities after the interviews are completed and the focus group facilities will not send any identifying information to RTI or CDC.

Once the potential participant comes to the study site and checks in, he/she will be given a consent form. The individual will be given time to read the consent form on his/her own and a trained RTI staff member will be available to answer any questions. If the participant agrees to be in the study, he/she will sign the consent form and be given a copy to keep for his/her records. Participants will be reminded that they can refuse to answer any question and they can stop being in the study at any time, without penalty. RTI staff will FedEx or personally take these forms back to RTI after the interviews are completed in each city. The consent forms will be stored in a locked file cabinet at RTI for the duration of the project. Once the project ends, the forms will be transferred to a locked RTI storage facility for three years. After three years, RTI staff will destroy the forms.

11. Justification for Sensitive Questions

Sensitive information will not be collected as part of this study.

12. Estimates of Annualized Burden Hours and Costs

The total annualized response burden is estimated at 115 hours. There is no change to the estimated total annualized response burden hours or cost as a result of the extension request. **Exhibits 12.1 and 12.2** provide details about how this estimate was calculated. Timings were conducted during our instrument development process to determine the overall burden per respondent. Administration of the screening instrument is estimated to take 10 minutes. Participation in an interview is estimated to take 1 hour. Each year we will complete 123 screening questionnaires (20 hours) and 82 physicians will participate in an interview (82 hours), and take a 10 minute paper and pencil survey (13 hours) totaling 115 hours. Each participant will also complete a 5 minute consent form (7 hours).

Exhibit 12.1. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	Responses Per Respondent	Average Burden Per Response (in hours)	Total Burden Hours
Emergency Medicine Physicians	Routine HIV Testing Screener	12	1	10/60	2
	Routine HIV Testing Interview	8	1	1	8
	Routine HIV Testing Paper & Pencil Survey	8	1	10/60	1
Prevention Is Care	<i>PIC</i> Screener	72	1	10/60	12
	<i>PIC</i> Interview	48	1	1	48
	<i>PIC</i> Paper & Pencil Survey	48	1	10/60	8
Partner Services	Partner Services Screener	39	1	10/60	6
	Interview (<i>Concept Testing</i>)	13	1	1	13
	Interview (<i>Materials Testing</i>)	13	1	1	13
	Partner Services Paper & Pencil Survey	26	1	10/60	4
	Total				115

In calculating the burden, we used the amount of \$66.79 per hour as an estimate of the average physician's hourly wage rate. We will continue to use the mean hourly wage for physicians and surgeons released from the United

States Department of Labor, Bureau of Labor Statistics
(May, 2005). Available online at:
<http://www.bls.gov/oes/current/oes291069.htm>. Actual hourly
wage rates will vary by physician credentials (e.g., wage
rates for IDS may be higher than the wage rates for PCPs).
The estimated annual cost to participants for the hour
burden for collections of information will be \$7,757.00.

Exhibit 12.2 Estimated Annualized Burden Costs
13. Estimates of Other Total Annual Cost Burden to

Respondents	Activity	No. of Respondents	No. of Response per Respondent	Average Burden per Response (in Hours)	Total Burden Hours	Hourly Wage Rate*	Total Respondent Costs**
Routine HIV Testing in Emergency Departments	Screeners	12	1	10/60	2	\$66.79	\$134
	Interview (Material Testing)	8	1	1	8	\$66.79	\$534
	Paper and Pencil Survey	8	1	10/60	1	\$66.79	\$89
Prevention Is Care (PIC)	Screeners	72	1	10/60	12	\$66.79	\$801
	Interview (Material Testing)	48	1	1	48	\$66.79	\$3,206
	Paper and Pencil Survey	48	1	10/60	8	\$66.79	\$534
HIV Partner Services	Screeners	39	1	10/60	6	\$66.79	\$434
	Interview (<i>Concept Testing</i>)	13	1	1	13	\$66.79	\$868
	Interview (<i>Material Testing</i>)	13	1	1	13	\$66.79	\$868
	Paper and Pencil Survey	26	1	10/60	4	\$66.79	\$289
Total					115		\$7,757

Respondents and Record Keepers

Respondents participate on a purely voluntary basis and, therefore, are subject to no direct costs other than their time to participate; there are no start-up or

maintenance costs. We do not require any additional record keeping.

14. Annualized Cost to the Government

The total annualized cost for the remainder of this study is estimated to be \$293,652. This includes the CDC FTEs and a contractor (**see Exhibit 14.1**). Details of the annualized costs are contractor's costs are based on estimates provided by the contractor who will carry out the data collection activities. This is the cost estimated by the contractor, RTI, and includes the estimated cost of coordination with the CDC, data collection, analysis, and reporting.

Exhibit 14.1. Estimated Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
<i>Direct Cost to the Federal Government</i>		
• CDC oversight of contractor and project	CDC Project Officer	\$60,521
	CDC Co-Principal Investigator	\$59,295
<i>Subtotal, Direct Costs to the Government</i>		\$119,816
<i>Contractor and Other Expenses</i>		
• Recruitment and Data Collection (Contractor)	Labor hours and Other Direct Costs	\$130,380
• Analysis and Reporting (Contractor)	Labor hours and ODCs	\$43,456
<i>Subtotal, Contracted Services</i>		\$173,836
TOTAL COST TO THE GOVERNMENT		\$293,652

15. Explanation for Program Changes or Adjustments

This is a request for a three year time extension. There is no change in burden requested or associated costs. The remaining interviews will be conducted to finish creating materials for the three campaigns. The remaining interviews from 0920-0775 were not conducted due to budget reductions and eliminations. Therefore all materials were not developed.

16. Plans for Tabulation and Publication and Project Time Schedule

Data from the interviews will be entered into an electronic data matrix by the RTI note taker during the data collection and stored on a password protected computer. Analysis of the interview data will start immediately after completion of data collection in each city and will be conducted under the supervision of a senior staff member with extensive experience in qualitative research. RTI will conduct thematic or ground theory analysis of the data to understand participants' reactions to the campaign messages in as rigorous and detailed manner as possible. RTI and CDC will review the preliminary data within one week after data collection is completed in each city via a debriefing conference call. RTI analysts will further analyze the data in the matrices and summarize results in three separate topline reports by phase and one final report. Data from the paper and pencil questionnaires will be keyed into Microsoft Excel and be reported in descriptive data tables with accompanying narrative in the topline and summary reports. The key events and reports to be prepared are listed in **Exhibit 16.1.**

Exhibit 16.1. Project Time Schedule

Activity	Time Schedule
Identify and reserve focus group facilities	1 month after OMB approval
Begin recruitment	1 month after OMB approval
Phase 1: Conduct interviews	2 months after OMB approval
Phase 1: Topline report due	4 months after OMB approval
Phase 2: Conduct interviews	17 months after OMB approval
Phase 2: Topline report due	19 months after OMB approval
Phase 3: Conduct interviews	32 months after OMB approval
Phase 3: Topline report due	34 months after OMB approval
Summary report due	35 months after OMB approval

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

We do not seek approval to eliminate the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.