Section A: Justification

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

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A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), Division of HIV/AIDS Prevention, requests OMB approval for a new formative research study to support CDC's efforts to develop three new social marketing campaigns. This study originally published in the 60 day Federal Register Notice titled as *"Formative Research to Develop Social Marketing Campaigns: Routine HIV Testing for Emergency Medicine Physicians, Prevention Is Care (PIC), and Partner Services"*. The goal remain the same but the Gynecologist and Obstetricians originally schedule has been replaced with Emergency Medicine Physicians for the Routine HIV Testing Campaign; a new component ("partner services") added; and a pencil and paper survey. The focus groups were eliminated and the number of individual interviews increased and the estimated annualized burden hours decreased. The purpose of the study is to conduct in-depth interviews with infectious disease specialists, primary care physicians, and emergency department physicians for the development the social marketing campaigns: Routine HIV Testing, Prevention is Care (*PIC)* and Partner Services.

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. An estimated 1,039,000 to 1,185,000 people are now living with HIV/AIDS in the United States (Glynn and Rhodes, 2005). Particularly worrisome is that an estimated 25% of HIV-infected persons may be unaware of their infection (Fleming et al., 2002).

In 2003, the CDC launched the Advancing HIV Prevention: New Strategies for a Changing Epidemic (AHP) initiative (CDC, 2003), which aims to reduce barriers to early diagnosis and to increase access to and use of quality medical care, treatment, and prevention services for people living with HIV. Early knowledge of HIV status is important for linking those who are HIV-positive to medical care and services that can reduce morbidity and mortality and improve their quality of life (KFF, 2005). Knowledge of one's HIV serostatus can also help prevent the spread of the infection to others, because those who are aware they are infected with HIV are significantly more likely to protect their partners from infection (Wenger et al., 1994; Kilmarx et al., 1998). Estimated annual transmission rates have also been found to be lower among those who are aware of their HIV status than among those who are unaware of their status (Holtgrave and Anderson, 2004). In support of AHP, CDC is developing three HIV social marketing campaigns for 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 conduct one time semi structured in person in-depth interviews with physicians to develop three social marketing campaigns (Routine HIV Testing, *PIC*, and Partner Services). CDC and RTI International will work together to conduct the interviews. We will use the results of these interviews to develop and pre-test campaign concepts, messages, and materials for the three social marketing campaigns: We will interview each physician only once and will be able to develop all campaign materials through the one time interviews. Through the in-depth interviews, we will 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 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. **Attachments 2** to **6** are the data collection instruments. Activities will be conducted in three phases over a three year period in 6 different cities. Phase 1 will focus on concept testing in 2 cities. Phase 2 will build on the results of phase 1 and focus on message testing in 2 different cities. In phase 3, we will develop campaign messages based on results obtained from phase 1 and 2. We will incorporate

the interview findings in designing social marketing materials. We will also disseminate the study results to the public through reports prepared for/by CDC and RTI and peer-reviewed journal articles where appropriate. All releases of information will be reviewed and approved by CDC.

3. Use of Improved Information Technology and Burden Reduction

Each interview will be tape recorded and used for preparing reports. Our data collection requires that we 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 an extensive review of the literature by examining several large periodical journal databases. In addition to reviewing published information, we searched for "gray" literature by exploring the Internet. WE also searched the internet using several Internet search engines, including Google, Yahoo, AltaVista, Medline, and Science Direct. We were unable to find duplication or the use of similar information. There is no other study that duplicates our proposed efforts.

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 provide the primary data needed to develop 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 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 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 CRF 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 published on December, 12, 2006 (Volume 71, Number 238, pages 74542-74543) solicited comments on Formative Research to Inform the Routine HIV Testing for gynecologists providing primary care services and *Prevention Is Care* (*PIC*) Social Marketing Campaigns. No comments were received. **Attachment 7** is the copy of the 60-day *Federal Register* notice.

B. The CDC study team collaborated with RTI International staff (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 each campaign and are listed below. No major problems were identified that could not be resolved.

Routine HIV Testing

After completion of the formative research, we will consult with several social marketing, behavior change, and evaluation experts for campaign development and evaluation, as needed.

We consulted with the following individuals at various times throughout 2005 and 2006 for development of campaign concepts, messages, and materials (see **Table 8.1**). We will continue consultation as needed.

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

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	**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

PIC

We consulted with the following individuals numerous times throughout 2005 and 2006 for development of campaign concepts, messages, and materials (see **Table 8.2**). We will continue consultation as needed.

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

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	**Raul Romaguera,** M.D. Associate Director for Prevention in Care 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) 639-2004 RRomaguera@cdc.gov

On February 1, 2006, CDC hosted an expert consultation with prominent providers in the field of HIV/AIDS who are involved in the treatment of persons living with HIV (see **Table 8.3**). Consultation objectives were to:

- Tap into the clinical experiences of the consultants to gather best practices for prevention in care.
- Gain insight from the consultants on the most effective ways *PIC* can be used to gain provider support to incorporate prevention into the routine medical care of persons living with HIV/AIDS on a regular basis.
- Discuss how the consultants can best support the campaign goals in their local areas and how they can help create a sphere of influence in support of the campaign.

Table 8.3. PIC Expert Consultation Participants

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	**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
Wayne Bockmon, M.D.—Staff Physician, Montrose Clinic 4706 Westslope Circle Austin, TX 78731 (512) 420-2314 kwb@austin.rr.com	**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
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	**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

Donald T. Evans, M.D.—Physician, Founder, AIDS Project Greater Danbury 115 Mount Pleasant Rd. Newton, CT (203) 426-5626 apgd99@aol.com	**Peter Shalit**, M.D., Ph.D.—Physician, Swedish Medical Center 1120 Cherry Street, #320 Seattle, WA 98104 (206) 624-0688 psmd@mac.com

Partner Services

We consulted with the following individuals numerous times throughout 2005 and 2006 for development of campaign concepts, messages, and materials (see **Table 8.4**). We will continue consultation as needed.

Table 8.4. Individual Consulted During the Development of the Partner Services Campaign

Samuel Dooley, MD Centers for Disease Control and Prevention Division of HIV/AIDS Prevention 8 Corporate Blvd. Mail Stop D-21 Atlanta, GA 30329 404.639.5229 office 404.639.0897 fax samuel.dooley@cdc.hhs.gov

In addition, we will 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 an honorarium to thank them for their time and effort in the study. The honorarium amounts are as follows:

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

The honorarium amounts 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. The honoraria are 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 honorarium 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 honoria 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 honoraria 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 honoraria will result in higher data validity as physicians become more engaged in the interview process. Participants will receive their honorarium immediately after completing their participation in the interview.

10. Assurance of Confidentiality Provided to Respondents

This data collection has received IRB approval from the CDC Human Research Protection Office (protocol #5166, expiration 7/30/08). The Formative Research to Develop Social Marketing Campaign-Routine HIV Testing for Emergency Medicine Physicians, Prevention Is Care, and Partner Services is in **Attachment 8**). RTI 's IRB approval is **Attachment 9**.

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 allow by law.

RTI will select and reserve focus group facilities in each city for each of the three campaigns and oversee the local focus group facilities' recruitment of participants. Recruitment staff will receive extension 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 Letter of Agreement (**Attachment A19**). 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 facilities 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 (**Attachments 10 to 12**). 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 194 hours. **Tables 12.1 and 12.2** provides 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 204 screening questionnaires (35 hours) and 136 physicians will participate in an interview (136 hours), take a 10 minute paper and pencil survey (23 hours).

Table 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,	Emergency Departments Study Screening	36	1	10/60	6
	Emergency Departments Material Testing	24	1	1	24
	Emergency Departments Paper & Pencil Survey	24	1	10/60	4
ID and PCP physicians	*PIC* Screener	81	1	10/60	14
	PIC Interview	54	1	1	54
	PIC Paper & Pencil Survey	54	1	10/60	9
All Physicians who treat HIV-positive persons	Partner Services Screener	87	1	10/60	15
	Interview (*Exploratory Research*)	18	1	1	18
	Interview (*Concept Testing*)	20	1	1	20
	Interview (*Materials Testing*)	20	1	1	20
	Partner Services Paper & Pencil Survey	58	1	10/60	10
	Total				194

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 used 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 $12,958.00.

Respondents	Activity	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden Hours	Hourly Wage Rate*	To Respo Cost
Routine HIV Testing in Emergency Departments	Emergency Departments Study Screener	36	1	10/60	6	$66.79	$4
	Emergency Departments Materials Testing	24	1	1	24	$66.79	$1,6
	Emergency Departments Paper and Pencil Survey	24	1	10/60	4	$66.79	$2
Prevention Is Care (PIC)	PIC Screener	81	1	10/60	14	$66.79	$9
	PIC Materials Testing	54	1	1	54	$66.79	$3,6
	PIC Paper and Pencil Survey	54	1	10/60	9	$66.79	$6
HIV Partner Services	Screener	87	1	10/60	15	$66.79	$1,0
	Interview (*Exploratory*)	18	1	1	18	$66.79	$1,2
	Interview (*Concept Testing*)	20	1	1	20	$66.79	$1,3
	Interview (*Materials Testing*)	20	1	1	20	$66.79	$1,3
	Paper and Pencil Survey	58	1	10/60	10	$66.79	$6
Total					**194**		**$12,9**

Table 12.2 Estimated Annualized Burden Costs

13. Estimates of Other Total Annual Cost Burden to 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 this study is estimated to be $408,412. This includes the CDC FTE s and a contractor. (**see Table 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.

Table 14.1. Estimated Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Cost to the Federal Government		
• CDC oversight of contractor and project	CDC Project Officer	$60,521
	CDC Co-Principal Investigator	$59,295
	Subtotal, Direct Costs to the Government	*$120116*
Contractor and Other Expenses		
• Recruitment and Data Collection (Contractor)	Labor hours and Other Direct Costs	$216,222
• Analysis and Reporting (Contractor)	Labor hours and ODCs	$72,074
	Subtotal, Contracted Services	*$288296*
	TOTAL COST TO THE COVERNMENT	**$408,412**

15. Explanation for Program Changes or Adjustments

There is no change in burden requested, as this is a new information collection.

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 **Table 16.1.**

Table 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.