Request for Sub-collection under the Approved Generic ICR:

Formative Research and Tool Development

OMB No. 0920-0840, Expiration 02/28/2016

Supporting Statement A

Formative Research to Development Social Marketing Campaigns: Prevention Is Care (PIC)

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Contact Person:

Nancy Habarta, MPH

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Centers for Disease Control and Prevention

1600 Clifton Rd. NE

Mailstop E-49

Atlanta, GA 30329

Telephone: (404) 639-2034

E-mail: eqq1@cdc.gov

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A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's Division of HIV/AIDS Prevention, (DHAP) requests OMB approval for a formative research study entitled, "Formative Research to Develop Social Marketing Campaigns: Prevention Is Care (PIC)" to support CDC's efforts to develop and refine materials (**Attachments 5.1-5.17**) for a social marketing campaign under the Formative Research and Tool Development Generic Clearance (OMB #0920-0840 expires 02/28/2016). The purpose of this study is to conduct in-depth interviews with health care providers (e.g. Infectious Disease Specialists and primary care physicians) and social service providers for the development of the PIC social marketing campaign. The study will consist of a series of in-depth interviews with 20 health care providers and social service providers in four cities. Participants will be recruited from areas with high HIV/AIDS prevalence and incidence such as Houston, TX; Atlanta, GA; Miami, FL; and Boston, MA. The sample will have a maximum of 80 respondents selected from professional recruiting facility databases.

Interviews will include pretesting draft materials for the PIC campaign. Providers will view draft materials and will be asked qualitative and quantitative questions to determine their reaction, comprehension, and perceived usefulness of the materials. Information will be gathered to inform the development and refinement of campaign messages and materials. Draft messages/concepts and materials will be pretested to obtain reactions regarding appropriateness, usability, and relevance to their practice.

According to recent estimates, approximately 1.2 million people are living with HIV in the United States. Centers for Disease Control and Prevention (CDC) HIV incidence rates indicate that more than 48,000 people were infected with HIV in 2009 (Prejean et al., 2011). Numerous social, economic, and demographic factors—such as stigma, discrimination, income, education, and geographic region—affect an individual's risk for HIV. Men who have sex with men (MSM), African Americans, and Hispanics/Latinos have higher incidence rates than other populations (CDC, 2012). Health care providers influence their patients' behaviors and are critical in facilitating HIV testing and prevention, and making HIV risk behavior screening a standard of care (CDC, 2003).

In 2003, a number of federal agencies, led by the CDC, released a set of recommendations for incorporating HIV prevention in the medical care of persons living with HIV (Centers for Disease Control and Prevention, 2003). The recommendations apply to the care of all HIV-infected persons, regardless of age, sex, and race/ethnicity. These recommendations are for all persons who provide medical care for HIV-infected persons, e.g. physicians, nurse practitioners, nurses, and physician assistants, and also may be useful to those, such as case managers, social workers, and health educators, who deliver prevention messages (Centers for Disease Control and Prevention, 2003). Essentially, we know that medical care providers can substantially affect HIV transmission by screening their HIV-infected patients for risky behaviors, communicating prevention messages, discussing sexual and drug use behavior, positively reinforcing changes to safer behavior, facilitating partner notification, counseling, and testing, and identifying and treating other sexually transmitted diseases (STDs).

The 2003 recommendations were part of a comprehensive plan to help prevent the spread of HIV by providing guidance to both private and public sector health care providers who deliver prevention messages and screening to patients living with HIV. An updated set of recommendations are anticipated for release in 2014. The new recommendations will update and expand on existing recommendations issued in 2003 by CDC, Health Resources and Services Administration (HRSA), National Institutes of Health (NIH), and HIV Medicine Association of the Infectious Diseases Society of America (HIVMA). These recommendations are being updated for several reasons, including the growing number and greater longevity of persons living with HIV in the United States, an availability of a larger set of effective clinical approaches to reduce transmission, and greater experience with promoting adoption of these clinical approaches at an individual or population level. The new recommendations will focus on anti-retro viral therapy (ART) initiation and adherence, retaining HIV-infected patients in care, and reducing HIV transmission by helping patients modify risky sexual behaviors. CDC created the Prevention *Is* Care (PIC) campaign to provide science-based prevention guidance and interventions that health care providers can incorporate into routine care of persons living with HIV.

A.1.2 Privacy Impact Assessment

The Privacy Act is not applicable to this collection. Recruitment facilities will be asked to sign a privacy agreement prior to the start of the study (**Attachment 1**). RTI will retain notes, audio files, and any other project-related documents on secure servers or in locked file cabinets; only project staff members will be able to access the servers via password-protected computers. Interview findings will be reported in summary form, and participants' names and identifying information will not be included in the findings. Identifiable information is kept separate from interview data, so that participants' responses cannot be linked with their names. All audio files will be destroyed three years after completion of the project. No identifiable information describing individual respondents will be included in the analyzed data and aggregate reports provided to CDC.

A.1.3 Overview of the Data Collection System

CDC's contractor, RTI International, in conjunction with professional focus group facilities, will implement qualitative interviews. The respondents for this study will be a maximum of 80 health care and social service providers selected from the facilities databases over a 12-month period. The facilities' data sets contain a large number of general practitioners and infectious disease providers. The study will work with volunteer respondents for product development and testing purposes. The goal is to obtain feedback specific on materials (**Attachments 5.1-5.17**) to support PIC communication initiatives.

A.1.4 Information to Be Collected

Data to be collected includes the following: sociodemographics; current HIV testing recommendations for patients; knowledge, attitudes, beliefs, and perceived social norms related to HIV testing; intentions regarding HIV testing; current practice standards regarding HIV screening; providers' self-efficacy about communicating with patients about HIV screening and partner notification; self-reported exposure to the PIC campaign; and reactions and receptivity to PIC campaign messages and materials (**Attachments 5.1-5.17**). The data collection will use (1) a 15-minute paper-and-pencil (PAPI) quantitative survey before the qualitative, in-person interview and (2) an in-person 60-minute interview

and 5 minute consent. **Attachments 2 and 3**, respectively, include a copy of the PAPI survey and interview guide.

We will screen participants to determine if they meet the study criteria. Participants will be asked questions about themselves and their practice (type of practice, specialty, years in practice, age, and gender) and the number of patients in their case load (overall and HIV-positive patients). CDC and RTI will have access to this information but records will not be stored with individually identifying information and procedures will be followed to limit the linkage of this information to response data as described in Section A.10. A copy of the screening instrument is attached as **Attachment 4**.

A.1.5 Identification of Web Site(s) and Web Site Content Directed at Children under 13 Years of Age

This information collection does not involve websites or website content directed at children less than 13 years of age.

A.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 health care providers (e.g. primary care physicians and Infectious Disease Specialists) and social service providers to develop and improve social marketing campaign materials (**Attachments 5.1-5.17**) for PIC. RTI International will conduct the interviews. We will use the interview results to develop, refine and pretest campaign concepts, messages, and materials. We will interview each participant only once and will develop and refine all campaign materials through the one-time interviews. Through the in-depth interviews, we will gain an understanding and identify participants'

- 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 education materials.

The social marketing campaign will increase the adoption of CDC's updated set of recommendations that are anticipated for release later in 2014. The new recommendations will update and expand on existing recommendations issued in 2003 by CDC, HRSA, NIH, and HIV Medicine Association of the Infectious Diseases Society of America (HIVMA). See **Attachments 2 and 3** for the data collection instruments. We will 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.

A.3 Use of Improved Information Technology and Burden Reduction

We will audio record each interview to use 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 participant consent, we will audio tape the interviews to capture all information and assist with report preparation.

A.4 Efforts to Identify Duplication and Use of Similar Information

The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention has verified that there are no other federal generic collections that duplicate the study types included in this request.

A.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.

A.6 Consequences of Collecting the Information Less Frequently

The activities involve a one-time collection of data over a 12-month period.

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

This request fully complies with regulation 5 CFR 1320.5.

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

For subcollection requests under an approved generic ICR, Federal Register notices are not required and none were published.

Exhibit A.8.1. Individuals Consulted During the PIC Campaign

Jo Ellen Stryker, PhD, MA National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Centers for Disease Control and Prevention 1600 Clifton Rd. NE Mailstop E-49 Atlanta, GA 30329 (404) 639-2071 gux6@cdc.hhs.gov	Nancy Habarta, MPH National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Centers for Disease Control and Prevention 1600 Clifton Rd. NE Mailstop E-49 Atlanta, GA 30329 (404) 639-2034 eqq1@cdc.hhs.gov
Jennifer D. Uhrig, PhD, MHA RTI International Center for Communication Science 3040 Cornwallis Rd. Research Triangle Park, NC 27709 uhrig@rti.org (919) 316-3311	Julia Kish Doto, PhD, MS RTI International Center for Communication Science 6110 Executive Boulevard, Suite 902 Rockville, Maryland 20852-3907 jkdoto@rti.org (301) 468-8280
Brian Southwell, PhD RTI International Center for Communication Science 3040 Cornwallis Rd. Research Triangle Park, NC 27709 bsouthwell@rti.org (919) 541-8037	

A.9 Explanation of Any Payment or Gift to Respondents

We will provide appreciation honorarium for providers who participate in the research. Honoraria were determined based on previous research and experience with conducting interviews with primary care providers and infectious disease specialists, recognizing that physicians are a difficult population to reach. Honoraria will vary by specialty or geographic region.

Honorarium amounts were determined based upon the time that physicians may have to take time away from their practice to come to the focus group facility and the type of physicians who are invited to participate. We are recruiting two different types of physicians, (1) infectious disease (ID) specialists and (2) primary care physicians. Initially, we will provide an honorarium of $150 for both types of physicians and then we will offer a refusal conversion of $250 if response rates are lower than expected.

The honoraria will encourage the physicians' cooperation and participation, and conveys appreciation for contributing to this important study. Numerous empirical studies (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999) have shown that honoraria can significantly increase response rates. 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. The proposed amount is slightly lower than quotes received from focus group facilities; however, we are confident that we will be able to recruit physicians.

Numerous studies show difficulties in recruiting physicians to participate in research (Berk & Jen, 1985; W. L. Cull, O'Connor, & Olson, 2010; William L. Cull, O'Connor, Sharp, & Tang, 2005;

VanGeest, Johnson, & Welch, 2007). One systematic review assessing ways to improve physician participation (VanGeest et al., 2007) found that researchers who provided higher incentives yielded higher odds of physician participation. Similarly, studies that provided monetary vs. non-monetary incentives had much higher odds for participation (VanGeest et al., 2007). Furthermore, a higher number of physicians are now paid on a fee-for-service basis and may be reluctant to leave their offices for an interview without adequate compensation. 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 honoraria rates currently range from $200 to $350 for physicians depending on specialty and geographic location.

An honorarium of $100 to $250 was utilized with success during a previous Prevention is Care (PIC) study titled: Formative Research to Develop Social Marketing Campaigns: Routine HIV Testing for Emergency Medicine Physicians, Prevention Is Care (PIC), and Partner Services (OMB #0920-0775, submitted in 2007). The amount was approved after demonstrating that a lower amount did not appear sufficiently attractive to physicians especially given that a higher number of physicians are now paid on a fee-for-service basis. The amount previously used was approximately seven years ago and thus our modest increase to begin at $150 for physicians has been updated for recruiting PCPs and IDS in 2014.

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.

A.10 Assurance of Privacy Provided to Respondents

This data collection was reviewed by CDC's Human Research Protection Office, and it was not deemed as human subjects research. See **Attachment 7**. The CDC has determined that the Privacy Act is not applicable.

A professional recruitment firm will identify, screen, and recruit potential participants using their proprietary recruitment list/database. The focus group facility will use additional recruitment methods, such as including flyers and notices at health care venues, as needed. Individuals who meet the screening criteria and agree to participate will be invited to attend a 1-hour interview. Before data collection, potential participants of the in-depth interviews will be sent a reminder letter or e-mails that also give directions to the study site. See **Attachment 8**. See **Attachment 4** for a copy of the provider screener. Recruitment facilities will be asked to sign a privacy agreement prior to the start of the study (see **Attachment 1** for a copy of the privacy agreement). The screener forms will be stored in a locked file cabinet at RTI throughout the project's duration. Once the project ends, the screener forms will be destroyed. RTI will retain notes, audio files, and any other project-related documents on secure servers; only project staff members will have access to the servers via password-protected computers. Interview findings will be reported in summary form and participants' names and identifying information will not be included in the findings. Identifiable information is kept separate from interview data so that participants' responses cannot be linked with their names. All audio files will be destroyed three years after completion of the project.

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.

Participants will be given time at the beginning of the interview to read the consent and ask questions. Providers will be provided with two copies of the informed consent: one to keep and one to sign or indicate consent and return.

During the interview, the moderator will go over key parts of the informed consent during the introduction to the interview. The moderator will inform participants that the interview is voluntary, and that they may choose not to answer any question and end participation at any time. The moderator also will inform participants that RTI will report findings in summary form so that participants cannot be identified and that their identifiable information will be kept secure and separate from the interview notes and audio recordings. For the provider interviews, the moderator will inform the participant that there is a note taker behind a one-way mirror and that CDC staff may be watching in person or via a live video stream. The informed consents include both the number for RTI's Office of Research Protection, in case participants have questions about their rights as a study participant, as well as the project director, in case participants have questions about the study itself. A copy of the provider consent form is attached as **Attachment 6** (two formats, one for Infectious Disease Specialists and one for primary care providers).

A.11 Justification for Sensitive Questions

We will not collect sensitive information from participants. However, there is a minimal risk that some questions may make respondent feel uncomfortable. The informed consent form includes a statement about this risk and informs participants that they may choose not to answer a particular question if they wish and/or end the study at any time without penalty (see **Attachment 6**).

A.12 Estimates of Annualized Burden Hours and Costs

We estimate the total annualized response burden at 154 hours. **Exhibits 12.1** and **12.2** provide details about how this estimate was calculated. Timings are based on our previous experience conducting research with this population to determine the overall burden per respondent. Screening instrument administration is estimated to take 10 minutes.

For eligible and interested participants and if time permits, we may mail the materials (**Attachments 5.1-5.17**) that will be discussed during in the interview in advance so participants can review the materials in advance of the interview. Participants who do not receive the materials in advance will be given time to review them independently at the focus group facility before the interview. Independent review of the materials (both offsite and onsite) is estimated to take 15 minutes. After independent review, participants will complete a 15-minute PAPI survey followed by participation in a 1-hour interview.

We will complete 160 screening questionnaires (27 hours). 80 participants will review materials (20 hours), take a 15-minute PAPI survey and participate in an interview (20 hours), provide consent (7 hours), and complete the interview (80 hours). The entire estimate totals 154 hours.

Exhibit A.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
Health care providers and Social service providers	Provider Screener	160	1	10/60	27
	Advanced review of materials	80	1	15/60	20
	Paper-and-pencil survey	80	1	15/60	20
	Consent	80	1	5/60	7
	Provider Interview Guide	80	1	1	80
	Total				154

In calculating annualized costs to physicians, we used $90.00 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 2013; 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 primary care physicians). The estimated annual cost to physician participants for the hour burden for the collection of information will be $13,860.00.

Exhibit A.12.2 Estimated Annualized Burden Costs

Activity	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Provider Screener	160	1	10/60	27	$90.00	$2,430.00
Advance review of materials	80	1	15/60	20	$90.00	$1,800.00
Paper-and-pencil survey	80	1	15/60	20	$90.00	$ 1,800.00
Consent	80	1	5/60	7	$90.00	$630.00
Provider Interview Guide	80	1	1	80	$90.00	$7,200.00
Total						$13,860.00

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

CDC does not anticipate providing start-up or other related costs to private entities.

A.14 Annualized Cost to the Federal Government

The contractor's costs are based on estimates provided by the contractor, who will carry out the data collection activities. With the expected period of performance, the annual cost to the federal government is estimated to be $197,470.90 (**Exhibit 14.1**). This is the cost estimated by the contractor, RTI, and includes the estimated cost of coordination with CDC, data collection, analysis, and reporting.

Exhibit A.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	$25,906
	CDC Co-Principal Investigator	$11,565
Subtotal, Direct Costs to the Government		*$37,471*
Contractor and Other Expenses		
Recruitment, data collection including honorarium costs, analysis and reporting (contractor)	Labor hours and other direct costs including honorarium	$160,000.00
Subtotal, contracted services		*$160,000.00*
Total cost to the government		**$197,471**

A.15 Explanation for Program Changes or Adjustments

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

A.16 Plans for Tabulation and Publication and Project Time Schedule

During data collection, the RTI note taker will enter data from the interviews into an electronic data matrix, which will be 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 1 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 four separate summary reports by city and one final report. RTI will key data from the PAPI survey into Microsoft Excel and be reported in descriptive data tables with accompanying narrative in the summary and final reports. **Exhibit 16.1** lists the key events and reports by city**.**

Exhibit A.16.1. Project Time Schedule for each City

Activity	Time Schedule
Identify and reserve focus group facilities	1 week after OMB approval
Begin recruitment	2 weeks after OMB approval
Conduct interviews	8 weeks after OMB approval
Topline report due	10 weeks after OMB approval

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

OMB Expiration Date will be displayed on necessary materials and documents.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

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