# Formative Research to Develop HIV Social Marketing Campaigns for Healthcare Providers

# Supporting Statement A Reinstatement OMB No. 0920-1182

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**Goal of the study:** To deepen our understanding of healthcare providers' interpretation and understanding of existing and emergent HIV prevention science; how providers use guidance or evidence-based approaches in their practices generally and with populations that have been largely overlooked (e.g., transgender individuals, people who inject drugs (PWID)); and to inform the development and/or revision of messages, concepts and materials for healthcare providers designed to support patient-provider communication about HIV testing, prevention, and care.

**Intended use of the resulting data:** CDC will use findings to develop and/or revise timely, relevant, clear, and engaging messages, concepts, and materials for healthcare providers under the *Let's Stop HIV* Together campaign in support of the U.S. Department of Health and Human Services' *Ending the HIV Epidemic: A Plan for America*.

Methods to be used to collect data: In-depth interviews and brief surveys.

**The subpopulation to be studied:** Healthcare providers, including primary care, and relevant specialties such as HIV medicine and infectious disease, physicians, physician assistants, and nurses.

**How data will be analyzed:** Thematic or grounded theory analyses of qualitative data and descriptive analyses of quantitative data.

**Impact of Covid-19 on Information Collection:** We do not anticipate challenges related to the COVID-19 pandemic in conducting these data collections as all data collection can be completed online.

#### 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 approval for a three-year 'Reinstatement with Change' of the information collection request (ICR) entitled, "Formative Research to Develop HIV Social Marketing Campaigns for Healthcare Providers" (OMB 0920-1182, expired May 31, 2020). This ICR supports information collection using in-depth interviews with healthcare providers in the United States, including physicians, physician assistants, and nurses who practice primary care or relevant specialties, including HIV medicine and infectious disease (hereafter, "healthcare providers") to inform the development and/or refinement of provider-focused messages, concepts, and materials under CDC's *Let's Stop HIV Together* social marketing campaign.

Approximately 1.1 million people are living with HIV in the United States. The CDC estimates that more than 37,000 people were diagnosed with HIV in 2018 (CDC, 2019a), with higher incidence rates observed among gay, bisexual and other men who have sex with men (MSM), African Americans, Hispanics/Latinos (CDC, 2019b), transgender communities (Clark et al., 2017), and people who inject drugs (PWID) (CDC, 2019b). To address the HIV epidemic in the U.S., the Department of Health and Human Services launched *Ending the HIV Epidemic: A Plan for America*, which is a cross-agency initiative aiming to reduce new HIV infections in the U.S. by 90% by 2030 (CDC, 2019c). CDC's *Let's Stop HIV Together* campaign (formerly known as *Act Against AIDS*) is part of the national initiative and includes tools and resources for healthcare providers who treat people at risk for or living with HIV (CDC, 2019d) that aim to

- encourage providers to test pregnant women for HIV to help reduce the number of infants born with HIV, promote routine HIV screening during patient visits per the CDC HIV Testing recommendations, and to prescribe pre-exposure prophylaxis (PrEP) and postexposure prophylaxis (PEP), when indicated, to prevent new HIV infections;
- help providers communicate with patients about HIV-related topics with the goal of improving outcomes on the HIV prevention and care continuum; and
- improve providers' capacity to deliver patient-centered care.

The materials developed for the *Together* campaign have made great strides in addressing health care providers' information needs; however, more research is needed to deepen our understanding of providers' interpretation and understanding of existing and emergent HIV prevention science; how providers use guidance or evidence-based approaches in their; and how to develop new or enrich existing provider materials to make them more informative, appealing, and useful. The information gathered through this data collection will allow CDC to develop and/or refine timely, relevant, clear, and engaging materials to support patient-provider communication to support HIV prevention, testing and care. For this information collection, CDC will oversee the data collection to be carried out by a contractor, assist in interpreting research findings, and spearhead dissemination activities.

A total of 2,850 hours were approved for this ICR (OMB No. 0920-1182) in 2017. Since the approval date, 143 burden hours have been used. The data collected from these information

collections was used to inform the development/refinement of messages, concepts, and materials for provider audiences. After the package expired, CDC decided to continue the information collection which is why we are requesting a reinstatement with change. Specifically, we are requesting an additional three years to continue information collections with priority audiences to further develop and refine materials under the *Let's Stop HIV Together* campaign in support of the national *Ending the HIV Epidemic* plan. Through this reinstatement, we plan to use the remaining approved 2,707 burden hours.

This study is authorized under U.S. Federal Code, 42 USC 241, Section 301 of the Public Health Service Act (see **Attachment 1**).

## A.2 Purpose and Use of the Information Collection

The purpose of this information collection request is to conduct semi-structured, in-depth interviews (in-person or via videoconference or telephone) with healthcare providers to inform the development and/or revision of health care provider-focused timely, relevant, clear, and engaging messages, concepts, and materials focused on HIV prevention, testing and care for the *Let's Stop HIV Together* campaign. A contractor will conduct the interviews. We will interview each participant only once and will develop and refine all campaign materials through the one-time interviews. The data collection will provide a deeper understanding of participants' information needs.

Key research questions for this formative research are presented in **Exhibit A.2.1**. The brief, web-based survey is shown in **Attachment 3** and the discussion guides are shown in **Attachments 4-7**.

## Exhibit A.2.1 Key Research Questions

- 1. What are providers' current practices for HIV prevention, testing, and care (e.g., including behavioral screening, partner notification, primary and secondary prevention, retention in care, ART adherence, prescribing PrEP, delivering patient-centered care, communicating about treatment as prevention and viral suppression)?
- 2. What are providers' knowledge, attitudes and beliefs about current recommendations for HIV testing, prevention, and care (e.g., PrEP, treatment as prevention)?
- 3. What are providers' perceived and actual barriers to implementing HIV prevention, testing and care guidelines and recommendations?
- 4. What types of tools and resources do providers need to help them implement HIV prevention, testing and care guidelines and recommendations and facilitate effective patient-provider communication?
- 5. What are providers' initial reactions to campaign messages, concepts and materials (e.g., visual appeal, format, design, content, usefulness, credibility)?
- 6. What are providers' preferred channels for obtaining new information on HIV

prevention, testing and care guidelines or practices?

As stated in *Section A.1*, we are requesting a reinstatement with changes, including reducing the burden hours (2017 request: 2,850; 2021 request: 2,707) and replacing the "Transgender Health" exploratory interview guide with the "Patient-Centered Care" exploratory interview guide. The changes will not have a negative impact on the data collection nor CDC's ability to answer key research questions. Reducing the burden benefits busy healthcare providers. Not only will fewer providers participate in the data collection, but we will also not need to screen as many people to achieve the desired sample size (and costs to the government will decrease, accordingly). Furthermore, all three exploratory interview guides are designed to get input on specialized populations, including transgender patients, so no information will be lost by eliminating the transgender health exploratory guide. Furthermore, an increased focus on patient-centered care will help CDC develop resources and tools that will enable healthcare providers to communicate more effectively with their patients, including transgender patients, about HIV-related topics.

#### A.3 Use of Improved Information Technology and Burden Reduction

Where possible and upon participant consent, we will audiotape the interviews to capture all information and assist with report preparation. Our data collection requires that we employ qualitative research methods through the use of one-time, in-depth interviews conducted inperson or via videoconference or telephone. The qualitative data collection will be complemented with data collected through a brief web-based survey. Use of web-based surveys reduces respondent burden by automating "skip" instructions rather than asking participants to interpret and implement the instructions themselves. This approach is less cognitively demanding and reduces the amount of time it will take participants to complete the survey. In addition, the survey will automatically place results in a format that can be read by our statistical analysis software. This functionality eliminates the potential for key stroke errors since research staff do not have to transcribe the data manually. See **Attachment 3a** for screenshots of the web-based survey.

#### A.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 through an Internet search. 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 for the present study.

#### A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

#### A.6 Consequences of Collecting the Information Less Frequently

These are ad hoc, one-time data collections over a three-year period to inform the development/revision of campaign materials for healthcare provider audiences. There are no legal obstacles to reduce burden. The information collections will provide the primary data needed to develop final materials. If we did not conduct this formative research, we would not be able to gather information from healthcare provider audiences needed to develop and pre-test campaign messages, concepts and materials before they are widely distributed. Our formative research process includes gaining an understanding of various attitudes, beliefs, behaviors, perceived needs, perceived benefits sought, and areas of concern to help improve implementation of HIV testing, prevention and treatment guidelines and recommendations and enhance patient-provider communication. Subsequently, messages, concepts and materials are developed or refined based on these results followed by testing with healthcare providers before they are widely disseminated.

#### A.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.

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

A 60-day Federal Register Notice was published in the Federal Register on March 8, 2021, vol. 86, No. 43; pp. 13388-13390 (**Attachment 2**). There were no public comments.

The CDC study team collaborated with the contractor on the study design, screening instruments, and data collection instruments. Contract staff are trained and experienced in conducting formative research and CDC recognizes the importance of gaining valuable insights from experts with experience working with healthcare provider audiences. Individuals consulted with and their roles are listed in **Exhibit A.8.1**. No major problems were identified that could not be resolved.

As needed, CDC will continue to conduct ad hoc consultations with subject-matter experts to obtain broad input from key experts early in the campaign development process to identify strengths and areas for improvement; and broadly discuss experts' recommendations for working with potential partners and leveraging pre-existing efforts to complement the campaigns.

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Exhibit A.8.1. Let's Stop HIV Together Campaign Evaluation Consultants

#### A.9 Explanation of Any Payment or Gift to Respondents

Participants will be offered a token of appreciation which is intended to recognize the time burden placed on respondents, encourage their cooperation, and convey appreciation for contributing to this important study. Initially, we will provide a token of appreciation of \$100 for all providers and then we will offer a refusal conversion of \$250 if response rates are lower than expected. Token of appreciation amounts were determined based upon the time that providers have to take time away from their practice to participate. We plan to recruit physicians, physician assistants, and nurses who practice primary care or relevant specialties, including HIV medicine and infectious disease.

Numerous empirical studies have shown that tokens of appreciation can significantly increase response rates (Abreu & Winters, 1999; Bentley & Thacker, 2004; Göritz, 2006; Permuth-Wey & Borenstein, 2009; Shettle & Mooney, 1999). Existing theories help to explain why and how tokens of appreciation motivate participation in interviews, focus groups and surveys, such as social exchange theory (Dillman, 1978), the norm of reciprocity (Groves, Cialdini, & Couper, 1992), economic exchange theory (Biner & Kidd, 1994), and leverage-saliency theory (Groves, Singer, & Corning, 2000). In addition to theory, there are psychological factors that underpin participation, including altruism and egoism, drives that balance the desire to be helpful with the need to further one's own self-interest. In consideration of knowledge gained from similar research and existing theories and psychological factors that underlie participation, we have determined that a token of appreciation is warranted for data collections conducted under this ICR. Based on OMB's guidance on factors that may justify provision of a

token of appreciation (Office of Information and Regulatory Affairs, 2016), we have determined that the following reasons apply:

Improved coverage of specialized respondents, rare groups, or minority populations: OMB guidance justifies the use of tokens of appreciation "to improve coverage of specialized respondents, rare groups, or minority populations" and defines specialized respondents as a highly selective group (OMB, 2016). The key audiences prioritized in this data collection include physicians and other healthcare providers. Healthcare providers have been challenging to recruit for formative research studies as they are a specialized, unique group of people whose time is limited and, thus, quite valuable (Asch, Connor, Hamilton, & Fox, 2000). A token of appreciation will ensure participation from a cross section of physicians, which will improve data quality by improving validity and reliability. Therefore, professional recruitment firms that recruit healthcare providers recommend a substantial token of appreciation to ensure adequate participation, and many will refuse to recruit for a project unless the token of appreciation is sufficient.

*Past Experience*. A token of appreciation of up to \$250 for primary care physicians and infectious disease specialists was approved under the OMB package #0920-1182. In our experience, a substantial token of appreciation has been more successful than lower tokens of appreciation in recruiting healthcare providers for research studies. Use of a lower token of appreciation may result in higher recruiting fees from the professional recruitment firms or refusal or withdrawal of some facilities from the bidding process for the research. Kim Johanson, a Vice President of recruiting for Schlesinger Associations, a market research firm that conducts over 6,000 healthcare studies annually, states "These are the [tokens of appreciation] needed to ensure success for recruiting in the markets specified. From our extensive history of recruiting, the amounts are based on the lowest amounts that have proven to be successful." (K. Johanson, personal communication, September 10, 2014).

*Data quality:* If we are unable to recruit sufficient numbers of providers to participate in the data collection, we will be unable to collect information to inform the development of new or revisions to existing messages, concepts, and materials nor will we be able to adequately test the messages, concepts and materials, which will limit our ability to determine if they are acceptable, understandable, motivating, etc. to the priority audiences, and avoid unintended negative consequences of messages/materials. This is particularly applicable when we consider that the data collection will include providers that give care to vulnerable subgroups, such as MSM and transgender individuals.

*Reduced data collection costs*: We anticipate that without the token of appreciation, recruitment and data collection costs will be much higher because we will need to screen more people to achieve the desired cooperation rate (McGrath, 2006) and recruit additional participants to make up for a higher rate of no-shows.

# A.10 Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CDC/ATSDR Privacy Officer, has assessed this package for applicability of 5 U.S.C. § 552a, and determined that the Privacy Act does not apply to the overall information collection (Attachment 11), for which personally identifiable information is being collected during recruitment. All information collected shall be kept private to the extent allowed by law. All individuals involved in data collection shall be trained concerning procedures and practices to ensure privacy of data and will be required to undergo ethics and protection of human subjects training through an accredited course (e.g., CITI). No personal identifying information, such as names, addresses, or phone numbers, will be collected during the interviews or maintained in any data files. However, personally identifiable information (including full name, address, phone, and email), is collected from participants during the screening steps of this collection. The collection of PII is covered under SORN # 09-20-0161: "Records of Health Professionals in Disease Prevention and Control Training Programs". However, no PII will be entered into a system of records. All PII will be kept separate from participant responses. Prior to data collection, participants will be given time to read the consent (Attachment 8) and ask questions. Providers will be offered a copy of the consent form to take with them, if they wish. During the introduction to the interview, the interviewer will go over key parts of the informed consent which will include informing participants of the following:

- 1. The interview is voluntary; participants may choose not to answer any question and end participation at any time.
- 2. The contractor 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.
- 3. For in-person interviews, there is a note-taker behind a one-way mirror and that CDC and/or contractor staff may be watching in person or via a live video stream. For telephone or videoconferencing, CDC staff and/or contractor staff may be listening to or observing the interview.

The informed consent includes both the telephone number for the contractor's IRB office, in case participants have questions about their rights as a study participant, as well as the project director, should participants have questions about the study itself.

CDC's contractor will implement all formative research for this study. Annually, we anticipate screening 1,138 individuals in order to obtain 569 interviews. Data may be collected in person or electronically (e.g., by phone or through virtual technologies). All data collection for this project will include participants from locations (states, counties, and territories) identified as priorities in the *Ending the HIV Epidemic* plan.

Participants for the in-depth interviews will be recruited by contractor staff or through local professional recruitment firms hired by the contractor (hereafter referred to collectively as "recruiters"). Based on the campaign component being developed and the priority audience(s), recruiters will screen each potential participant on certain criteria, such as specialty (and subspecialty, if applicable), their practice (e.g., number of years in practice, practice setting, age, gender) and the number of patients in their case load (overall and HIV-positive patients). The recruiters will collect the names, email and physical addresses, phone numbers and emails of the eligible individuals who have agreed to participate and have been given an interview appointment. For the in-depth interviews, this personally identifiable information (PII) will be used to provide appointment reminders. All PII will be kept in locked file cabinets or secure online servers and will be destroyed after the in-depth interviews are completed. No PII will be sent to CDC. The recruiters will be asked to sign a privacy agreement prior to the start of the study (**Attachment 10**). Contractor staff will take notes and audio record each in-depth interview for the purpose of analyzing the data and completing the final reports. The entire data collection will be a one-time, in-depth individual interview and a one-time, web-based survey per individual.

All data collection will take place through an annual series of in-depth interviews with a total of 569 providers (**Attachments 4-7**) and consist of one of four types of information collection (exploratory research, message testing, concept testing, or materials testing). The questions for the exploratory round of research will vary and reflect the type of message, concept, or material being developed (see **Attachments 4a-4c**). Questions on the message (**Attachment 5**), concept (**Attachment 6**), and materials (**Attachment 7**) testing guides will be the same across all individuals and assess providers' initial reactions to campaign materials (e.g., visual appeal, format, design, content, usefulness, credibility); preferred channels for obtaining new information on guidelines or practices; and interest in provider resources and patient education materials. Based on the results of the message testing, the messages presented may be modified and retested to increase overall receptivity among the campaign audiences. Any retesting of messages will take place within the amount of burden hours and number of participants as detailed for message testing in **Exhibit A.12.1 Estimated Annualized Burden Hours**.

All providers participating in the in-depth interviews will also take a 15-minute brief, web-based survey. (see **Attachment 3**).

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

This project received approval through a Project Determination from the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, which has deemed this activity as program evaluation and not human subject research. **Attachment 12** shows the Project Determination for the prior ICR. A new project determination is not required because there are no changes to the previously approved scope of work.

All participants will be assured that the information collected will be used only for the purpose of informing the development/refinement of campaign messages, concepts, and materials, and will be kept secure to the extent allowable by law, as detailed in the sample consent form (see **Attachments 8**). We will obtain verbal consent for telephone or video-conference interviews. Once a potential participant provides verbal consent, we will proceed

with the interview. Participants will be assured that their answers to screener (see **Attachment 9**), and data will not be shared with anyone outside the research team and that their names will not be reported with responses provided. Participants will be told that the information obtained will be combined into a summary report so that details of individual responses cannot be linked to a specific participant.

#### Sensitive Questions

We will not collect sensitive information from participants. However, there is a minimal risk that some questions may make the participant 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 (**Attachment 8**).

## A.12 Estimates of Annualized Burden Hours and Costs

The total estimated annualized response burden hours are 902. **Exhibits A.12.1** and **A.12.2** provide detail about how this estimate was calculated. Time estimates are based on our previous experience conducting data collections with healthcare providers. We anticipate screening 1,138 individuals to obtain 569 respondents annually (**Attachment 9**); screening will take approximately 10 minutes per individual (190 annual burden hours). An estimated 569 participants will complete a 15-minute web-based survey (**Attachment 3/3a**) annually (142 annual burden hours). There will be a total of 569 participants who complete in-depth interviews of any type annually (**Attachments 4-7**); interviews will take approximately one hour per individual (569 annual burden hours).

				Average	
			No. of	Burden per	Total
Type of		No. of	Responses Per	Response	Burden
Respondent	Form Name	Respondents	Respondent	(in hours)	Hours*
Healthcare	Screener (Att 9)	1,138	1	10/60	190
providers	Web-based survey				
	(Att 3, 3a)	569	1	15/60	142
	Exploratory guide –				
	PwP** and retention				
	in care (Att 4a)	95	1	1	95
	Exploratory guide –				
	Patient-centered care				
	(Att 4b)	95	1	1	95
	Exploratory guide –				
	HIV prevention (Att				
	4c)	95	1	1	95
	Message testing	95	1	1	95

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden per Response (in hours)	Total Burden Hours*
F	guide (Att 5)	F	<b>F</b>	(	
	Concept testing guide				
	(Att 6)	95	1	1	95
	Materials testing				
	guide (Att 7)	95	1	1	95
	TOTAL				902

\*Rounded to the nearest hour.

\*\**PwP=Prevention with positives*.

In calculating annualized costs to healthcare providers, we used \$96.85 per hour as an estimate of the average hourly wage rate. To establish this amount, we used the mean hourly wage for general internal medicine physicians (Bureau of Labor Statistics, 2019). Actual hourly wage rates will vary by credentials (e.g., wage rates for physician specialists will be higher than the wage rates for nurses). The estimated annual cost to participants will be \$87,354.

		No. of	Average			
	No. of	Responses	Burden per		Total	Total
	<b>Respond-</b>	Per	Response	Hourly	Burden	Respondent
Form Name	ents	Respondent	(in hours)	Wage Rate	Hours*	Costs**
Screener	1,138	1	10/60	\$96.85	190	\$18,373
Web-based						
survey	569	1	15/60	\$96.85	142	\$13,777
Exploratory						
guide – PwP***						
and retention in						
care	95	1	1	\$96.85	95	\$9,201
Exploratory						
guide – Patient-						
centered care	95	1	1	\$96.85	95	\$9,201
Exploratory						
guide – HIV						
prevention	95	1	1	\$96.85	95	\$9,201
Message testing						
guide	95	1	1	\$96.85	95	\$9,201
Concept testing						
guide	95	1	1	\$96.85	95	\$9,201
Materials testing						
guide	95	1	1	\$96.85	95	\$9,201

#### Exhibit A.12.2 Estimated Annualized Burden Costs

Form Name	No. of Respond- ents	No. of Responses Per Respondent	Average Burden per Response (in hours)	Hourly Wage Rate	Total Burden Hours*	Total Respondent Costs**
TOTAL						\$87,354

\*Rounded to the nearest hour.

\*\*Rounded to the nearest dollar.

\*\*\*PwP=Prevention with positives.

**A.13** Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers There are no other costs to respondents or record keepers.

#### A.14 Annualized Cost to the Federal Government

The annualized cost to the federal government is \$484,033. The contractor's costs are based on estimates provided by the contractor who will carry out the data collection activities and includes the estimated cost of coordination with CDC, data collection, analysis, and reporting (**Exhibit A.14.1**). CDC personnel, including a Contracting Officers' Representative (COR), will be responsible for obtaining CDC approvals, providing project oversight and participating in analysis and dissemination of the results.

Item/Activity	Details	\$ Amount			
CDC oversight of	60% of FTE GS-13 Behavioral Scientist and 15%	\$84,033			
the contractor and	of FTE GS-13 Health Communication Specialist:				
project	CDC oversight of contractor and project				
Recruitment, data	Labor hours and ODCs	\$400,000			
collection					
including					
honorarium costs,					
analysis and					
reporting					
(contractor)					
Total \$484,033					

#### Exhibit A.14.1 Government Costs

FTE = full-time equivalent; ODC = other direct cost

## A.15 Explanation for Program Changes or Adjustments

This is a reinstatement request for ICR 0920-1182. We are requesting changes to reduce the burden by 48 hours, which is the differences of the hours that were used in the original ICR, and replace the "Transgender Health" exploratory interview guide with the "Patient-Centered Care" exploratory interview guide. The changes will not have a negative impact on the data

collection nor CDC's ability to answer key research questions. *Section A.2* discusses the rationale for these changes.

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

Data from the interviews will be stored on a password protected computer, cleaned, coded, and analyzed to identify themes, patterns, and unique insights offered by participants in as rigorous and detailed manner as possible. The contractor will conduct descriptive analyses of the data from the screener and brief, web-based survey, develop results tables, and summarize results in narrative form. When possible, analysts will triangulate results from the qualitative interviews with the results from the survey and highlight notable differences by key audience segments (e.g., physicians, nurse practitioners, PCPs, specialists). Results from each round of data collection will be summarized in a topline report and/or PowerPoint slide deck. The key events and reports to be prepared are listed in **Exhibit A.16.1**.

Activity	Time Schedule		
Identify and reserve professional	1 month after OMB approval		
recruitment firms			
Begin recruitment	1 month after identifying and		
	reserving recruitment firms		
Conduct first round of interviews	1 month after recruitment begins		
Draft topline report	1 month after data collection ends		
Final topline report and/or PowerPoint	1 month after receiving comments		
Slide Deck	on draft topline report		

#### Exhibit A.16.1 Project Time Schedule

We anticipate the first data collection taking place within one month of receiving OMB approval. Data collection for all other data collections under this Generic ICR will follow a similar time schedule over the three-year period. We will disseminate the study results to the public through reports prepared for/by CDC and the contractor. Where appropriate, we will also disseminate results through peer-reviewed journal articles and conference presentations. All releases of information will be reviewed and approved by CDC prior to release.

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

The display of the OMB expiration date is not inappropriate.

# **A.18 Exceptions to Certification for Paperwork Reduction Act Submissions** There are no exceptions to the certification statement.

#### REFERENCES

- Abreu, D. A., & Winters, F. (1999). Using monetary incentives to reduce attrition in the survey of income and program participation. *Proceedings of the Survey Research Methods Section of the American Statistical Association*.
- Asch S, Connor SE, Hamilton EG, Fox SA. Problems in Recruiting Community-based Physicians for Health Services Research. J Gen Intern Med. 2000;15(8):591-599.
- Bentley, J. P. & Thacker, P. G. (2004). The influence of risk and monetary payment on the research participation decision making process. *J Med Ethics*, 30(3):293-298.
- Biner, P. M., & Kidd, H. J. (1994). The interactive effects of monetary incentive justification and questionnaire length on mail survey response rates. *Psychology and Marketing*, 11(5), 483–492.
- Bureau of Labor Statistics (2019). Bureau of Labor Statistics (BLS). (2019). May 2019 National Occupational Employment and Wage Estimates United States, Healthcare practitioners and Technical Occupations. [Data table]. Retrieved from https://www.bls.gov/oes/current/oes\_nat.htm#00-0000
- Centers for Disease Control and Prevention (CDC). (2019a). Estimated HIV Incidence and Prevalence in the United States, 2010-2016. HIV Surveillance Supplemental Report, 24(1). Published February 2019. Accessed on March 1, 2020.
- Centers for Disease Control and Prevention (CDC). (2019b). Diagnoses of HIV Infection in the United States and Dependent Areas, 2018. HIV Surveillance Report, 30. Retrieved from: <u>https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-</u> <u>2018-vol-30.pdf. Published November 2019</u>. Accessed on March 1, 2020.
- Centers for Disease Control and Prevention (CDC). (2019c). Ending the HIV Epidemic: A Plan for America. Retrieved from: <u>https://www.cdc.gov/endhiv/index.html</u>. Published February 2019. Accessed on March 1, 2020.
- Centers for Disease Control and Prevention (CDC). (2019d). Let's Stop HIV Together. Retrieved from: <u>https://www.cdc.gov/stophivtogether/index.html</u>. Retrieved from: <u>https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-</u> <u>supplemental-report-vol-24-1.pdf</u>. Published 2019. Accessed on March 1, 2020.

- Centers for Disease Control and Prevention. HIV Among Transgender People. <u>http://www.cdc.gov/hiv/risk/transgender/index.html. Published April 15</u>, 2015. Accessed on October 7, 2015.
- Centers for Disease Control and Prevention. HIV Surveillance Report, 2011; vol. 23. <u>http://www.cdc.gov/hiv/pdf/statistics 2011 HIV Surveillance Report vol 23.pdf</u>. Published February 2013. Accessed November 10, 2014.
- Centers for Disease Control and Prevention, Health Resources and Services Administration, National Institutes of Health, American Academy of HIV Medicine, Association of Nurses in AIDS Care, International Association of Providers of AIDS Care, National Minority AIDS Council, and Urban Coalition for HIV/AIDS Prevention Services. Recommendations for HIV Prevention with Adults and Adolescents with HIV in the United States, 2014. 2014. <u>http://stacks.cdc.gov/view/cdc/26062</u>
- Clark, H, Babu, AS, Wiewel, EW, Opoku, J, Crepaz, N. Diagnosed HIV Infection in Transgender Adults and Adolescents: Results from the National HIV Surveillance System, 2009-2014. *AIDS Behavior*, *21*(9): 2774-2783.
- Dillman, D. A. (1978). Mail and telephone surveys: The total design method. New York: Wiley.
- Garcia-Perez LE, Álvarez M, Dilla T, Gil-Guillén V, Orozco-Beltrán D. Adherence to therapies in patients with type 2 diabetes. *Diabetes Therapy*. 2013 Dec 1;4(2):175-94.
- Göritz, A. S. (2006). Incentives in web surveys: Methodological issues and a review. *International Journal of Internet Science*, *1*, 58–70.
- Groves, R. M., Cialdini, R. B., & Couper, M. P. (1992). Understanding the decision to participate in a survey. *Public Opinion Quarterly*, *56*, 475–495.
- Groves, R. M., Singer, E., & Corning A. D. (2000). A leverage-saliency theory of survey participation: Description and illustration. *Public Opinion Quarterly*, 64, 299–308.
- McGrath DE. An incentives experiment in the US consumer expenditure quarterly survey. In: Proceedings of the Survey Research Methods Section of the American Statistical Association 2006 Aug.

- Office of Management and Budget (2016). Questions and Answers When Designing Surveys for Information Collections. Retrieved from <u>http://www.whitehouse.gov/sites/default/files/omb/inforeg/pmc\_survey\_guidance\_2006.p</u> <u>df</u>.
- Permuth-Wey, J. & Borenstein, A.R. (2009). Financial remuneration for clinical and behavioral research participation: ethical and practical considerations. *Ann Epidemiol*, 19(4):280-285.
- Rubin RR, Peyrot M, Siminerio LM. Health care and patient-reported outcomes: results of the cross-national Diabetes Attitudes, Wishes and Needs (DAWN) study. *Diabetes Care*. 2006 Jun 1;29(6):1249-55.
- Shettle, C., & Mooney, G. (1999). Monetary incentives in U.S. government surveys. *Journal of Official Statistics*, *15*, 231–250.
- Stryker JE, Beck AD, Primo SA, Echt KV, Bundy L, Pretorius GC, Glanz K. An exploratory study of factors influencing glaucoma treatment adherence. *Journal of Glaucoma*. 2010 Jan;19(1):66.