

Positive Health Check Evaluation Trial

Supporting Statement A
OMB No. 0920-New

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Goal: To evaluate the effectiveness of Positive Health Check (PHC), an online tool created by RTI and CDC that delivers tailored evidence based prevention messages to HIV positive patients, on improving clinical outcomes and retention in care of HIV positive patients with unsuppressed viral loads.

Intended Use: The evaluation trial results will be disseminated among all relevant stakeholders. The research findings will inform recommendations about adopting the PHC intervention at HIV clinics.

Methods: Four clinical sites will implement the PHC intervention trial (Atlanta, GA VA Medical Center, Tampa, FL Hillsborough County Health Department, Newark, NJ Rutgers Infectious Disease Practice and New Orleans, LA Crescent Care). Sites will conduct a systematic PHC telephone outreach to patients who have a viral load ≥ 200 , who are newly diagnosed, who are not in care (defined as patients whose last attended appointment at the clinic was more than 12 months ago), or have missed appointments to engage patients back in care. Patients who are successfully reengaged in care will be eligible to participate in the study.

Subpopulation: The primary study subpopulation will be persons with viral load lab result of ≥ 200 copies/mL, newly diagnosed patients, patients not in care (last attended appointment was more than 6 months ago).

Analysis: The statistical analysis will compare primary and secondary outcomes between participants in the treatment condition versus participants in the control condition.

A. JUSTIFICATION

A. 1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of HIV/AIDS Prevention (DHAP) requests a 3-year approval for a new data collection called "Positive Health Check Evaluation Trial."

CDC awarded a cooperative agreement to Research Triangle International (RTI) in September 2015 to conduct the Positive Health Check Evaluation Trial. The goal of the evaluation trial is to test the effectiveness of Positive Health Check (PHC), a web-based video intervention for reducing viral load in people living with HIV (PLWH), reducing sexual risk, and improving medication adherence and retention in healthcare. Information will also be collected to describe participating clinics' experiences with PHC implementation.

Background, Need and Circumstances Motivating the Request

HIV transmission continues to be an urgent public health challenge in the United States. According to the Centers for Disease Control and Prevention (CDC), approximately 1.2 million people are living with HIV (CDC, 2016). In 2014, an estimated 44,073 people were diagnosed with HIV (CDC, 2014a). Gay and bisexual men, particularly young African American gay and bisexual men, are most affected. Of those living with HIV in the United States, about 1 in 8 are unaware of their infection status (CDC, 2016).

Antiretroviral treatment (ART) can be used to suppress the plasma HIV viral load (VL) of people living with HIV (PLWH). Those who are treated with ART—compared with those who are not—have a substantially reduced risk of transmitting HIV sexually (Attia, Egger, Muller, Zwahlen, & Low, 2009), through drug sharing (Wolfe, Carrieri, & Shepard, 2010), or from mother to child (Sturt, Dokubo, & Sint, 2010). However, it is estimated that only 30% of all people who are infected with HIV in the United States, those who are diagnosed and undiagnosed, are virally suppressed (Bradley et al., 2014). Among people diagnosed with HIV 54.7% are virally suppressed (CDC, 2016). Retaining PLWH in healthcare and supporting adherence are important prevention strategies that lead to decreases in risk behaviors, enhanced clinical outcomes, and a reduction in transmission risk

(Simoni, Pearson, Pantalone, Marks, & Crepaz, 2006). In 2009, the HIV Medicine Association included a new recommendation for the healthcare of PLWH, stating that the “emphasis should be placed on the importance of adherence to care rather than focusing solely on adherence to medications” (Mugavero, Norton, & Saag, 2011). The process of engagement in HIV/AIDS medical care is a complex issue, incorporating linkage to care, retention, and reengagement. Effective prevention programs are urgently needed to support linkage to and retention in care, adherence to care, and reduced HIV transmission risk among diverse PLWH. CDC is contributing to the building of these prevention programs through several efforts including studies such as “CoRECT” (OMB #0920-1133, Exp. 08/31/2019), which aims to re-engage HIV patients who have fallen out of care; “APTCare” (OMB #0920-1002, Exp. 12/31/2016) which aims to improve adherence and prevention of HIV transmission; and THRIVE (OMB #0920-1178, Exp. 4/30/2020), which aims to strengthen coordination of care across a variety of services for men who have sex with men of color, who are HIV positive or at high risk of contracting HIV.

To keep PLWH in care and assist clinicians who serve them, innovative and engaging intervention strategies are needed. Computer-based tools that deliver prevention messages to patients and signal important information to providers have shown promise in changing HIV risk and adherence behaviors (Hersch et al., 2013; Kurth et al., 2014; Lustria, Cortese, Noar, & Glueckauf, 2009; Noar, Black, & Pierce, 2009; Pellowski & Kalichman, 2012). These interventions can also facilitate patient-clinician communication (Lewis, DeVellis, & Sleath, 2002) and provide patients with highly relevant tailored information, which has been shown to be more effective than one-size-fits-all prevention messaging approaches (Noar, 2011; Noar et al., 2009).

To enhance HIV prevention efforts, implementable, effective, scalable interventions are needed that focus on enhancing prevention and care to improve the health of and reduce HIV transmission risk among PLWH. Online interventions that can use technology in clinic settings, ensure low clinic staff burden and cost (Page, Horvath, Danilenko, & Williams, 2012), and allow for easy content updates that will facilitate timely responses to new information in the field of HIV are an effective strategy that can be taken to scale (Noar, 2011). Emerging evidence shows that “video doctors” can reduce sexual risk and drug risk among PLWH (Gilbert et al., 2008) and enhance adherence (Fisher et al., 2011). Internet-based dissemination channels also facilitate quick and low-cost national dissemination of interventions

(Ownby, Waldrop-Valverde, Jacobs, Acevedo, & Caballero, 2013). Previous studies leveraging the potential for digital interventions have been limited, however, by reliance on self-reported outcomes (Gilbert et al., 2008), have not been tailored to address patients' changes in adherence behaviors (Fisher et al., 2011), have not used randomization or experimental designs (Bachmann et al., 2013), have had high attrition (Bachmann et al., 2013), or have used small sample sizes (Hersch et al., 2013). Despite these limitations, evidence is emerging that web-based interventions that use video doctors, specifically, show promise in changing risk behaviors and supporting adherence (Gilbert et al., 2008; Kurth et al., 2014; Noar, 2011; Noar et al., 2009; Noar & Harrington, 2012).

Positive Health Check (PHC) is a new, web-based tool designed to meet this need. PHC is based on earlier computer-based interventions that were proven efficacious for HIV prevention, e.g., "Video Doctor" (Gilbert et al., 2008) and Lifewindows (Fisher et al., 2011), however, the PHC intervention approach is innovative in multiple ways. First, it uses an interactive video doctor to deliver tailored messages that meet specific patient needs related to adherence, sexual risk reduction, engagement in care, mother-to-child transmission, and drug use. This approach capitalizes on evidence-based tailored messaging strategies that have been shown to be more effective than a one-size-fits-all approach (Kreuter, 2000; Noar, Benac, & Harris, 2007; Noar et al., 2011). Second, PHC is designed specifically to support patient behavior change by providing useful tips to practice between visits. These tips are patient driven and populated on a handout while patients use the PHC intervention, thereby increasing engagement and the likelihood of success. This is important because patient engagement has been shown to change health outcomes and reduce healthcare costs (Green, Hibbard, Sacks, Overton, & Parrotta, 2015). Third, PHC supports patient-provider communication by also generating a set of questions that patients would like to ask their provider. These behavior change tips and questions are also populated on a Patient Handout (see PHC Sample Patient Handout in Attachment 16) that patients may share with their provider. As such, PHC supports patients and providers during their clinical encounter and promotes communication. Fourth, this intervention, while designed to be used in the clinic waiting room, can also be accessed from home or other locations, making it more easily accessible for patients. Since PHC is a web-based intervention, the security features built into the security encrypted website (with login credentials required) are in

place whether accessing PHC from the clinic or another location. Increasing the potential implementation strategies and intervention reach is a proven strategy to affect population health (Glasgow, Eckstein, & Elzarrad, 2013). Finally, the PHC intervention has been designed from the onset for wide-scale dissemination. Its flexible web-based strategy provides access on multiple devices and platforms.

This approach makes PHC a promising intervention strategy to improve public health in communities that have a high incidence of HIV infection. However, before PHC can be supported for broader dissemination, the intervention needs to be rigorously evaluated to assess intervention outcomes. If shown to be effective, long-term, PHC can be brought to scale and disseminated widely online at a relatively small cost to support large number of PLWH with their HIV care and treatment.

The primary goal of the data collection for this project is to evaluate the effectiveness of Positive Health Check (PHC), an online video tool created by RTI and CDC that delivers tailored evidence-based prevention messages to HIV positive patients. PHC is designed to improve HIV patients' viral load suppression and retention in care. Viral load is the amount of HIV in the blood of someone who is HIV-positive. When viral load is very low (called viral suppression, with less than 200 copies per milliliter of blood), the virus is unable to multiply and destroy the person's immune system, and it greatly reduces the chance of transmitting HIV. (Note that when viral load is greater than 200 copies per milliliter of blood, the viral load is not suppressed and the patient is at greater risk of transmitting HIV and experiencing poor health outcomes.) The primary study population will be persons with viral load lab results of ≥ 200 copies/mL (unsuppressed viral load), newly diagnosed patients, and patients not in care (last attended appointment was more than 12 months ago). Participants enrolled in the study will be randomly assigned to either the intervention or control group. Patients in the intervention arm will be expected to complete PHC intervention up to three times in a 12-month period. Patients randomized to the control arm will not use the intervention. Information will be collected from all enrolled patients and their electronic medical records (EMR).

The PHC evaluation trial will be conducted at four clinical sites: the Atlanta VA Medical Center (Atlanta, GA), Hillsborough County Health Department (Tampa, FL), Rutgers Infectious Disease Practice (Newark, NJ) and Crescent Care (New Orleans, LA). In addition to the

information collected to assess patient-level outcomes, information will be collected from clinic staff to characterize the barriers, facilitators, and costs associated with implementing PHC.

This proposed information collection is authorized under Section 301(a) of the Public Health Services Act (42.U.S.C.241) (**Attachment 1**).

A.2 Purpose and Use of the Information Collected

The overarching goal is to inform best practices for HIV clinics. The proposed PHC evaluation study has four primary objectives: 1.) Implement a randomized trial to test the efficacy of the PHC intervention for improving clinical health outcomes, specifically viral load and retention in care. Information will be collected to describe behavioral and clinical characteristics of persons with elevated viral load, and changes in those characteristics; 2.) Conduct a feasibility assessment to determine strategies to facilitate implementation and integration of PHC into HIV primary care clinics; 3.) Collect and document data on the cost of PHC intervention implementation; and 4.) Document the standard of care at each participating clinic. Findings from activities 2, 3, and 4 will be used to develop a strategic plan to increase the visibility and adoption of the PHC intervention in HIV clinics. Dissemination strategies aim to spread knowledge and the associated evidence-based interventions on a wide scale within or across geographic locations, practice settings, and social and other networks of end users such as patients and healthcare providers (Lomas, Brook, Power, Chalmers, & Peto, 1993; National Institutes of Health, 2007, Sep 10-11). Detailed information about each objective, and the source(s) of information collected for this purpose, is provided below.

Project Goal	Data Source	Respondents	Timing/Frequency
Aim 1-- Implement a	Date of Diagnosis	Patients in Treatment Arm	Once, at enrollment

randomized trial to test the effectiveness of the PHC intervention for improving clinical health outcomes, specifically viral load and retention in care.	(Attachment 6)		following consent.
	PHC Tailoring Questions (Attachment 7)	Patients in Treatment Arm	3 times over the study period beginning at enrollment.
	Electronic Medical Record(EMR) (Attachment 8)	All enrolled patients (passive data collection for treatment arm and control arm)	Every 3 months for 10 collections beginning in Month 3 of Implementation.

Aim 1--Implement a randomized trial to test the effectiveness of the PHC intervention for improving clinical health outcomes, specifically viral load and retention in care.

In order to determine whether the PHC video tool is improving the health of HIV patients, the first aim of the study will measure in the treatment and control groups, changes in the following variables by calculating the number and proportion of HIV infected individuals who experienced having:

1. HIV-1 viral load suppression (less than 200 copies/mL within 12 months after the date of randomization into the study).
 - Data source is HIV primary care clinic laboratory reports
 - These data will be used to measure the primary outcome of the study which is changes or increased viral load suppression.
2. Durable HIV-1 viral load suppression [two suppressed viral load results (less than 200 copies/mL)at least three months apart within 18 months from the date of randomization].
 - Data source is HIV primary care clinic laboratory reports
 - These data will be used to measure the primary outcome of the study which is changes (improvement) in viral load suppression.
3. ART initiation (received a prescription for ART within 90 days from the date of randomization)
 - Data source is HIV primary care clinic records

- These data will be used to measure ART initiation which if taken correctly, will improve health outcomes.
4. Attended one clinic visit within 90 days of the date of randomization. This is the retention in care outcome.
 - Data source is HIV primary care clinic patient appointment records
 - These data will measure patients' clinic attendance which is linked to improved health outcomes.
 5. Attended two visits at least three months apart within 12 months of the date of randomization. This is the Engaged in Care outcome.
 - Data source is HIV primary care clinic patient appointment records.
 - These data will measure patients' sustained clinic attendance which is linked to improved health outcomes.

These data will be obtained from the Electronic Medical Record (EMR) and other relevant databases from study clinics (**Attachment 8**).

Aim 1 requires the use of data collection instruments. The PHC intervention trial informed consent is included as **Attachment 9**.

Each patient enrolled in the treatment arm will be asked their date of diagnosis (**Attachment 6**). Included in the intervention are PHC tailoring questions (**Attachment 7**). The tailoring questions dictate which educational videos and information patients receive while using the PHC intervention.

Project Goal	Data Source	Respondents	Timing/Frequency
<i>Aim 2</i> -- Conduct a qualitative feasibility	Clinic Staff Survey (Attachment 10)	3-5 clinic staff involved in PHC	at the beginning of the study and then 4/yr for 3

assessment to determine strategies to facilitate implementation and integration of PHC into HIV primary care clinics	Individual or small group interviews with Clinic Staff Qualitative Interview Guide(Attachment 11)	implementation Staff involved in implementing PHC who also completed the Clinic Staff Survey	years at the beginning of the study and then 4/yr for 3 years (administered one month after online Clinic Staff Survey)
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Aim 2-- Conduct a qualitative feasibility assessment to determine strategies to facilitate implementation and integration of PHC into HIV primary care clinics

1. In order to determine whether the PHC video tool is feasible for implementation in HIV primary care clinics the following data will be collected.
 - Data sources are qualitative interview and survey data collected from staff implementing the PHC video tool.
 - These data will assess how PHC fits into routine clinical practice, how often and how many patients were offered the tool, and how PHC impacts patient-provider communication. The data will be used to improve clinics' strategies for integrating PHC into daily operations, key to the success of the intervention.
2. In order to document patients' user experience navigating through the tool modules the following data will be collected.
 - Data source is the de-identified anonymous backend data from the PHC video tool.
 - These data will be used to understand and build strategies to improve patient user experience with the PHC video tool.

Aim 2 requires the use of data collection instruments. Please see these instruments in the Attachments cited below.

Attachment 10: PHC feasibility assessment which includes a 15 minute online clinic staff survey every 3 months of the 3-year study period. As clinics gain experience with PHC they will refine their implementation strategies. Collecting data at 3-month intervals allows

CDC to capture important information on the feasibility of adopting and implementing PHC in clinic environments.

Attachment 11: Individual or small group interviews using the Clinic Staff Qualitative Interview Guide. The interviews will last approximately 40 minutes and will be conducted in the first project month then at every 3 months.

Project Goal	Data Source	Respondents	Timing/Frequency
<i>Aim 3--</i> Collect and document data on the cost of PHC intervention implementation	Non-research labor cost questionnaire (Attachment 12)	Clinic staff who participate in implementing the PHC intervention	(1) one month after intervention implementation start; (2) six months after implementation start; and (3) 12 months after implementation start
	PHC labor cost questionnaire (Attachment 13)	Clinic staff who participate in implementing the PHC intervention	(1) one month after intervention implementation start; (2) six months after implementation start; and (3) 12 months after implementation start
	PHC non-labor cost questionnaire (Attachment 17)	Clinic staff who participate in implementing the PHC intervention	Once a month after intervention implementation

Aim 3-- Collect and document data on the cost of PHC intervention implementation

In order to determine the cost of implementing PHC in HIV primary care environments, this aim requires data on cost factors that will be

collected by the 4 HIV clinics participating in the study. Data for this aim will be gathered as follows:

- Data sources are questionnaires that will be filled out by designated clinic staff.
- These data will be used to measure cost factors for staff time, computer equipment and office supplies (fax, printer, etc.)

Aim 3 requires the use of a data collection instruments. Please see the instruments in the Attachments cited below.

Attachment 12: Clinic staff who participate in implementing the PHC intervention will complete the attached PHC non-research labor cost questionnaire.

Attachment 13: Clinic staff who participate in implementing the PHC intervention will complete the attached PHC labor cost questionnaire.

Clinics will submit these data to RTI three times: (1) after the first month of PHC intervention implementation; (2) after the 6th month of PHC intervention implementation; and (3) after the 12th month of PHC intervention implementation. Data will be collected using the clinics' systems and is part of understanding the costs of implementation to the clinics.

Attachment 17: Clinic staff who participate in implementing the PHC intervention will complete the attached PHC non-labor cost questionnaire.

Clinics will complete Attachment 17 on a monthly basis throughout the PHC intervention implementation. These data will also be collected using the clinic's systems and helps understand costs of implementation as it relates to non-labor research costs.

Clinics will be asked to report labor and non-labor costs associated with implementing the intervention for each PHC program activity category in addition to indirect and overhead expenditures. The seven program activities categories include: (1) staff orientation and preparation; (2) patient identification and recruitment; (3) intervention delivery; (4) mobile device management; (5) patient outreach; (6) report generation; and (7) administration/general oversight.

Project Goal	Data Source	Respondents	Timing/Frequency
<i>Aim 4--</i> Document the standard of care at each participating clinic	Standard of Care Questionnaire (Attachment 14)	The medical director at each clinic	(1) 1 month into Implementation; (2) 14 months into Implementation; and (3) 27 months into Implementation (estimated to take approximately 90 min. each)

Aim 4-- Document the standard of care at each participating clinic

1. In order to determine whether the PHC video tool is improving the health of HIV patients, the fourth aim of the study will document each clinic's standard of care provided to HIV patients.
 - Data Source: Questionnaire documenting descriptive data on clinics' standard of care.
 - These data will be used to determine to what extent if any patients' health outcomes in the study can be attributed to variation in clinics' medical standard of care provided to HIV patients enrolled in the study.

The medical director at each site will provide information on their clinic's standard of care. Site contacts will identify the medical director and RTI will contact the medical director at each site through email or by phone.

Aim 4 requires the use of forms and data collection instruments. The Standard of Care Questionnaire is in **Attachment 14**.

A.3 Use of Improved Information Technology and Burden Reduction

One hundred percent of the proposed information collection used to evaluate the effectiveness of the PHC intervention (Aim 1) will be collected electronically. Patients will use their study ID to log in to the intervention at all three visits.

CDC will collect user metrics from the PHC also referred to as backend data. These data, captured via the PHC tool, include the PHC tailoring questions (**Attachment 7**) related to ART, adherence, clinic attendance, and behaviors that may increase risk of HIV transmission as well as process data (modules visited, pathways followed within each module, and amount of time spent in each module and in the tool overall).

For all participants, EMR data will be collected every three months. Biometric data from the EMRs such as patients' viral load and STD test results are more accurate and reliable than self-reported data on these metrics and electronically can be collected systematically in a more time-efficient manner. Depending on each clinic's system, some data may also be collected from other electronic systems. For example, information on patient attendance at primary care visits may not be collected in the clinic EMR. The clinic will gather data regarding patient attendance from their electronic scheduling system and provide this data to RTI. Dates of scheduled clinic appointments are considered identifiable information so we will work with each clinic's Institutional Review Board (IRB) to ensure privacy and other regulatory rules are followed. The data collected from the EMR and/or other electronic systems includes laboratory results, ART prescriptions, appointment attendance, STD test results, and demographic information (**Attachment 8**). The sites will collect historical EMR data for 24 months prior to the date of randomization. The consent form informs participants that we will collect EMR data for the 24 months prior to randomization and up to 18 months after randomization. We will use Python or another program to harmonize data before entering it into the master database. Additionally, the survey completed by staff to assess the feasibility of implementing PHC will be administered online via Qualtrics.

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

PHC intervention was developed by CDC in collaboration with RTI. There has not been a rigorous evaluation conducted on the PHC intervention tool. We performed a comprehensive search of the literature to identify relevant information and none was found. The PHC video is unique. Thus, the proposed data collection does not duplicate any prior efforts and will provide important information in improving health outcomes of HIV-positive people and preventing new infections.

A.5 Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

A.6 Consequences of Collecting the Information Less Frequently

We have determined that the frequency of data collection provides enough data to conduct a rigorous evaluation of the PHC intervention without overburdening study participants, including the participating clinics. The consequences of collecting data less frequently would jeopardize the evaluation of the longer-term effects of intervention and would jeopardize the scientific value of the evaluation we intend to conduct.

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

A 60-day Notice was published in the Federal Register on **November 3, 2016, Volume 81, Number 213, Pages 76590-76591 (Attachment 2)**. No public comments were received.

The persons outside the agency consulted for the PHC Evaluation Trial are Drs. Lisa Hightow-Weidman and Carol Golin, both from the University of North Carolina. They have consulted on study design and procedures, reviewed measures, provided input on the PHC Principal Investigator's meeting, and advised on clinical outcome measurement.

A.9 Explanation of Any Payment or Gift to Respondents

Recruiting participants with HIV infection and retaining them is central to the success of the proposed effectiveness study. In order to correctly power our study we are requiring the four clinics to recruit and enroll a total of 1,010 HIV patients. The PHC study population of interest is comprised of HIV positive patients, many of whom are not doing well with their HIV treatment and care. Many have elevated viral loads, have missed clinic appointments, have fallen out of care or are new to care. The eligibility criteria for the study are that patients must be 18 years of age or older, diagnosed with HIV, English-speaking, attending one of the four HIV primary care clinics and meet at least one of the following criteria:

- o Most recent viral load lab result of ≥ 200 copies/mL
- o Attended an initial HIV appointment with a provider at one of the four clinics within the past 12 months

- o Out of care (last attended appointment at the clinic was more than 12 months ago).

PLWH are considered a vulnerable population because they are stigmatized and marginalized, sometimes living on the fringes of the mainstream society and economy. In addition, the PHC study will recruit and enroll minority groups who may be stigmatized and marginalized due to their race/ethnicity. Minorities often distrust medical and social institutions and may be difficult to enroll (Arnett et. al 2016; Benkert et. al 2006; references in **Attachment 3**).

Because of the challenges faced by this population described above, it will be necessary to offer incentives to ensure patients' enrollment and retention in the study for both the treatment and control groups. Regarding incentives, Grady (2005; reference in **Attachment 3**) specifically recommends that the control and treatment groups be treated similarly, "as both are contributing to the development of generalizable knowledge to benefit others." Expectations for participants randomized into the treatment group are to allow access to medical and other clinic records such as appointment scheduling, use PHC three times in three consecutive clinic visits and to use talking points from their printed PHC Patient Handout to guide their questions and conversation during their appointment with their HIV provider (see PHC Sample Patient Handout in Attachment 16). PHC study participants randomized into the treatment group are also expected to practice their personally-selected behavior change strategies ("tips") before their next clinic visit which are noted on their Patient Handout. Patients enrolled in the control group will receive standard of care.

During recruitment, and upon patient consent, PHC project coordinators will carefully describe to patients the incentives (called "tokens of appreciation") and ensure that they understand the expectations of the research and the schedule and requirements for receiving incentives. The project coordinators will inform patients that when participating in the study they would receive two gift cards, each of a \$50 value. Project coordinators and patients will not know who will be randomized into the treatment or control groups. The project coordinator will explain to participants randomized to the treatment group that the first gift card would be provided immediately following the completion of the patients' first use of PHC. The patient would return the tablet to the project coordinator, receive their Patient Handout, receive the gift card and then head back to their scheduled appointment with their provider. The project coordinator will also explain to patients in the

treatment group that at their 12 month visit to the clinic at the end of the study, another token of appreciation will be provided after completing engagement with the PHC tool and returning the tablet. For patients randomized into the control group, the project coordinator will explain that the patient will receive the first gift card upon study enrollment and consent, and will receive the second gift card at the end of their 12 month appointment with their provider.

The purpose of the second token of appreciation is to help retain participants in the study. Retention in the study could be precarious due to the difficulties described above faced by the population targeted for this study. Table B1 in Supporting Statement B shows for each clinic the number of HIV patients with retention in care and/or adherence issues which are represented by the number of patients not virally suppressed. This is the very population that we are recruiting into the study, along with new patients (see Table B1). Drs. Golin and Hightow-Wideman who are consultants on this study, experts in the field of HIV and have successfully conducted many studies with the PLWH population informed the PHC study team that we will need to provide study participants with tokens of appreciation in order to achieve participants' study completion and to achieve our study goals.

The 12 month data collection point is critical to this study. The data provided to us for viral load at the 12 month point will be used to measure our primary study outcome, viral load suppression. The study will assess to what extent after patients' exposure(s) to the PHC tool improves viral load suppression. The entire study hinges on this critical 12 month viral load data point. The literature demonstrates that providing tokens of appreciation to ensure participants' study completion is essential for study success and is therefore a tool used widely used in research (Dowshen 2012; Cornelius et al. 2013; Uhrig et al. 2013; Grady 2005). Grady (2005; reference in Attachment 3) specifically recommends that "in longitudinal or long-term studies, where certain data points are critical to the study, it may be appropriate to use escalating incentives or completion bonuses..." (Grady 2005). However, we are proposing that the second token of appreciation remain at the \$50 gift card value, and that we not increase the value of the gift cards.

In previous studies tokens of appreciation have been shown to increase study participant response rates, which in turn improve the validity and reliability of the data (Abreu and Winters 1999; Shettle and Mooney 1999; full references in **Attachment 3**) which is of utmost

importance in this scientific study. In fact, the results of several studies support the use of incentives. A meta-analysis of survey methodologies (Church 1993; reference in **Attachment 3**) found that cross-sectional studies using incentives yielded an average increase in response rates of 19.1 percentage points. Edwards et al. (2002, reference in **Attachment 3**) reported similar results in a subsequent meta-analysis. With few exceptions, reports of more recent studies are consistent with results reported by Church, and Edwards et al. For example, Jackle and Lynn (2008, reference in **Attachment 3**) found that tokens of appreciation in a longitudinal study decreased attrition at all visits.

In cases where a clinic's standard of care outreach and appointment scheduling procedures have not been successful, PHC outreach will be used to contact by telephone and schedule a clinic appointment with those patients who do not have an appointment scheduled for the 12 month data collection point. During that outreach conversation, patients will be reminded of the second 12 month gift card. The PHC outreach worker will work closely with clinic staff to schedule the appointment. One crucial reason for offering the second token of appreciation at the 12 month data collection point is that receipt of the token of appreciation is attached to the patient using the PHC tool for the second or third time and the patient will visit the clinic lab for blood work, thereby providing the patients' critical 12 month data point for viral load. To summarize, for patients through the clinics' standard of care who have scheduled a clinic appointment during the 12 month data collection point, no reminders will be made of the second gift card. However, patients who require outreach telephone calls will be reminded of the gift card only during those outreach calls in order to schedule the 12 month clinic visit.

In order to arrive at a figure for the proposed level of incentive, the Positive Health Check team reviewed the literature (see Table A.1), consulted colleagues with extensive experience conducting research trials and held several hours of discussion. We propose that \$50 is a reasonable value for gift cards and that this amount is in the ballpark of the studies of a similar nature documented below. We also assert that the proposed gift cards are acceptable and appropriate for the norms of conducting research in the HIV community (Grady 2005; reference in **Attachment 3**) and represent the best efforts of the Positive Health Check team to design a study that will be acceptable to and appropriate for participating HIV patients and HIV clinics and allow us to reach our desirable sample size. See Table A.1

Table A.9-1. Tokens of appreciation amounts provided in similar studies

Publication	Study Population	Data Collection Type	Amount
Dowshen et al. (2012)	HIV-positive youth aged 14-29 (to explore the efficacy of text-messaging intervention to promote ART adherence)	Survey at baseline and at weeks 6, 12, and 24	\$200 (\$40 per survey)
Muessig et al. (2013)	African American MSM aged 18-30 (to inform the development of a text messaging intervention)	One-time focus group preceded by a brief survey	\$50 gift card
George et al. (2012)	African American and Latino MSM aged 18-25 (to explore current texting practices and the feasibility/acceptability of text messaging as a means of conducting sexual health promotion)	One-time brief survey plus focus group	\$40
Cornelius et al. (2013)	African Americans aged 13-18 (to examine the efficacy, feasibility, and acceptability of a mobile phone-based HIV prevention)	Survey at baseline, 1 month, and 3 months	\$50 upon completion of the 3-month survey
Uhrig et al. (2012)	HIV-positive MSM (to explore the preliminary efficacy of a text-messaging intervention to promote ART adherence, retention in care, and risk reduction)	Survey at baseline and at 3 months	\$55 (\$25 for the baseline and \$30 for the follow-up survey)

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

The CDC NCHHSTP Associate Director of Science Office reviewed this submission and determined that the Privacy Act is not applicable to the information collection because personally identifiable information (PII) will not be collected as part of this study. Only de-identified data are sent to CDC.

RTI will not receive patient names, medical record numbers, social security numbers, or personally identifiable information. All records will be identified by a unique study ID. Study IDs will be linked to medical record numbers only on a clinic computer or server and neither CDC nor RTI will be able to back convert a study ID into a medical record number. Data collected as part of the study will be stored on a password-protected project computer or local server at the clinic in an encrypted database. Clinics will de-identify data by removing names and EHR numbers and replacing them with the patient's study ID. Three of the clinic sites will send data to RTI using a password-protected secured FTP site. Each site will have their own FTP site to ensure that clinics do not have access to each other's data. The VA clinic has opted to record the data on a CD and have it shipped via overnight shipping to RTI according to their security protocols. The data on the CD will be encrypted. Once data has been downloaded by RTI, it will be removed from the FTP sites and the disc will be destroyed.

Protection of participant records also includes the following:

- CDC will not receive patient names, initials, medical record numbers, or contact information; all patients will be identified by a unique Study ID number.
- All data from the project transmitted to CDC will be encrypted and stored on a secure CDC server. All encryption device systems will be FIPS 140-2 compliant (federal standard).
- Project staff at each site will complete the computer-based National Institutes of Health ethics training annually and provide proof of course completion to CDC; project staff will also complete their institution's required training.

- Manuscripts and presentations only will report aggregated information and will not contain any identifying information that can be traced back to a particular patient.

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

IRB Approval

The protocol for PHC intervention trial has been reviewed and approved by RTI's Institutional Review Board (IRB) (**Attachment 5**). Additionally, three of the four clinics will have obtained IRB approval from their own institution's IRBs (one of the clinics does not have an IRB and will come under the RTI IRB) (**Attachment 5**). RTI has received an approved request for a waiver of informed consent from their IRB for the cost collection activities. These data will not include personal or sensitive information. The approved consent forms for the PHC intervention trial, the Clinic Staff Survey and the Clinic Staff Qualitative Interview Guide are included as **Attachments 9, 10, and 11**.

The objectives of the PHC intervention trial cannot be accomplished without the collection of sensitive information regarding HIV risk, such as sexual behavior, injection drug use behavior, as well as medical history and demographics. Collection of these data will be used to test the efficacy of the PHC intervention for improving clinical health outcomes, specifically viral load and retention in care.

Sensitive Questions

The context in which questions will be asked helps to overcome their potential sensitivity and to emphasize to the respondent the legitimate need for the information:

- a. Nearly all questions allow for respondents to skip the question or respond with "don't know"
- b. Consent forms make it clear that the study is sponsored by CDC and implemented by RTI and that the information will be put to important uses (**Attachment 9**).
- c. Assurances about the privacy of the data are reiterated in the consent forms.
- d. Participants will complete the PHC intervention using headphones and a privacy screen to ensure privacy while completing the

intervention in the waiting room or another private location that is to be determined by each site.

- e. Participants will be fully informed about the types of questions contained in the intervention. We will also clearly state that their answers are private.
- f. Participants will be completing the tool before their clinic visit; therefore, if they do experience any concerns, they will be able to discuss them promptly with their HIV care provider.
- g. Each clinic will follow their procedures for protecting patient information.
- h. Data will be reported in aggregate and quotes of any responses will be anonymous. Names will be removed from all transcriptions of qualitative interviews.

A.12 Estimates of Annualized Burden Hours and Costs

Information will be collected from and about a total of 1,010 study participants. One-half of the respondents enrolled in the study will be assigned to the intervention group (N=505) and one-half of respondents will be assigned to the control group (N=505). OMB approval is requested for 3 three years, thus the total annualized number of respondents is 337 and the annualized number of respondents in each assignment group is 168. Recruitment will occur primarily in Year 1 with follow-up for some respondents completed in Year 2. To meet total recruitment goals for the study, some respondents may be recruited in Year 2, with follow-up completed in Year 3.

All enrolled participants will be asked to complete a Date of Diagnosis Form (**Attachment 6**). The estimated burden per response is 1 minute. This is the only form completed by respondents in the control group.

Each participant in the intervention group will complete the patient tailoring questions within the PHC intervention tool three times over a period of approximately 12 months. The estimated burden per response is 5 minutes (**Attachment 7**).

Additional information about control group respondents and intervention group respondents will be obtained from electronic medical records (EMR). The burden of processing EMR data is incurred primarily by the contractor, and is accounted for as a study cost. However, the burden table includes an allowance for a clinic data manager at each clinic who will facilitate transmission of EMR and other requested clinic data for all study participants (control group

and intervention group). The collection and transmittal of EMR data by data managers is estimated to take 16 hours per response and will occur quarterly (**Attachment 8**). The total number of clinics is 4 and the annualized number of clinics is 1.

Three to five (3-5) staff members from each clinic will be participate in 2 information collections scheduled on an approximately quarterly basis. The maximum number of respondents is 20 (4 clinics X 5 staff members per clinic). For purposes of annualizing burden, these information collections are represented in the burden table with 20 respondents and an annualized frequency of 4. These information collections include the Clinic Staff Survey (**Attachment 10**; average burden per response of 15 minutes) and the Clinic Staff Qualitative Interview Guide (**Attachment 11**; average burden per response of 40 minutes).

One clinic staff member from each clinic will complete the Non-research labor cost questionnaire (**Attachment 12**) and the PHC labor cost questionnaire (**Attachment 13**). The estimated burden per response for each questionnaire is 90 minutes. These questionnaires will be completed 3 times over the 3-year period of the study. For purposes of annualizing burden, these questionnaires are represented in the burden table as 4 respondents per questionnaire, with an annual frequency of 1.

One clinic staff member from each clinic will complete the PHC non-labor cost questionnaire (**Attachment 17**). The estimated burden per response for each questionnaire is 30 minutes. These questionnaires will be completed on a monthly basis over the 3-year period of the study at each of the 4 participating clinics. Thus, the annual frequency is 12 and 4 respondents are indicated for this questionnaire for the purposes of annualizing burden.

Similarly, the medical director of each clinic will complete the Standard of Care Questionnaire (**Attachment 14**) 3 times over the 3-year clearance period. The estimated burden per response is 90 minutes. The annualized effort is represented as 4 respondents (one medical director per clinic) and an annual frequency of 1.

The total estimated annualized burden is 419 hours.

Table A12A. Estimate of Annualized Burden Hours					
Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in Hrs)	Total Response Burden (in Hrs)
Patients Enrolled in the PHC Evaluation Trial	Date of diagnosis question (Att 6)	337	1	1/60	6
	PHC tailoring questions (Att 7)	168	3	5/60	42
Staff in PHC Evaluation Clinics	Electronic Medical Record (EMR) (Att 8)	4	4	16	256
	Clinic Staff Survey (Att 10)	20	4	15/60	20
	Clinic Staff Qualitative Interview Guide(Att 11)	20	4	40/60	53
	Non-research labor cost questionnaire (Att 12)	4	1	1.5	6
	PHC labor cost questionnaire (Att 13)	4	1	1.5	6
	Standard of Care Questionnaire (Att 14)	4	1	1.5	6
	PHC non-labor cost questionnaire (Att 17)	4	12	30/60	24
Total					419

The annualized cost to respondents for the burden hours is estimated to be \$9,739.69; details are provided in Table A12.B. The estimates of hourly wages were obtained from the U.S. Department of labor (Bureau of Labor Statistics Wage Data (<http://www.bls.gov/news.release/pdf/ecec.pdf>)).
<http://www.bls.gov/oes/current/oes434111.htm>

Table A12B. Estimated Annualized Burden Costs				
Type of Respondent	Form Name	Total Burden Hours	Hourly wage rate	Total respondent costs
Enrolled participants	PHC tailoring questions	42	\$22.13	\$929.46
	Date of diagnosis question	6	\$22.13	\$132.78
Clinic Staff	Clinic Staff Survey	20	\$22.13	\$442.60
	Clinic Staff Qualitative Interview	53	\$22.13	\$1,172.89
	Non-research labor cost questionnaire	6	\$22.13	\$132.78
	PHC outreach labor cost questionnaire	6	\$22.13	\$132.78
	PHC non-labor cost questionnaire	24	\$22.13	\$531.12
	EMR Data Collection	256	\$22.13	\$5,665.28
	Standard of Care Questionnaire	6	\$100.00	600.00
Total		419		\$9,739.69

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

There are no other costs to respondents associated with this proposed collection of information.

A.14 Annualized Cost to the Government

This collection is being funded by the Cooperative Agreement [RFA-PS-15-001](#). The annualized cost to the government is **\$1,755,400.75**. The cost of this project for the three years is estimated to be **\$5,266,202.25**.

Expense Type (Based on FY17 dollars)	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government		
	Positive Health Check Personnel	
	Behavioral Scientist-14 (1) 100%	\$118,263.00
	Behavioral Scientist-14 (1) 5%	\$5913.15
	Behavioral Scientist-14 (1) 5%	\$5913.15
	Behavioral Scientist-13 (1) 50%	\$50,040.50
	Behavioral Scientist-12 (1) 30%	\$25,248.60
	Behavioral Scientist-12 (1) 30%	\$25,248.60
	Data Manager (contractor) (1) 30%	\$25,248.60
	Biostatistician-14 (1) 5%	\$5913.15
	Site Visits (4 trips x 2 staff)	\$12,000
	Total direct costs to federal government	\$273,788.75
Contractor and Other Expenses*	Cooperative Agreement#RFA-PS-15-001 .	
	Salary and Wages	\$117,407
	Travel	\$11,028
	Materials	\$13,541
	Consultants	\$12,000
	Subawards	\$1,081,894
	Shipping/postage	\$3,478
	Miscellaneous	\$98,500
	Indirect	\$143,764

	Total contractor and other expenses	\$1,481,612
	TOTAL COST TO THE GOVERNMENT	\$1,755,400.75

*Salary estimates were obtained from the US Office of Personnel Management salary scale at <http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2015/ATL.pdf>.

A.15 Explanation for Program Changes or Adjustments

This is a new data collection.

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

Data collection will be conducted during the 3-year period after OMB approval. Data analysis will occur from month 30 through month 36 which is within 6 months of final data collection. The following is a brief overview of the PHC intervention trial timeline.

Table16.A Project Time Schedule

Activity	Time Schedule
Initiate recruitment	Immediately after OMB approval
Conduct the PHC trial (36-month period)	1 month through 3 years after OMB approval
Conduct PHC feasibility data collection activities with staff	1 months through 3 years after OMB approval
Conduct cost data collection activities	1 months through 3 years after OMB approval
Analysis	Starting in month 30 and continuing until month 36 of the study period.
Publication	Within 12 months of completing information collection

CDC plans to disseminate the evaluation trial results among all relevant stakeholders (Lomas, Brook, Power, Chalmers, & Peto, 1993; National Institutes of Health, 2007, Sep 10-11). The findings will be presented at in-service trainings and professional conferences, and will be published in professional journals.

A.17 Reasons(s) Display of OMB Expiration Data is Inappropriate

The display of the OMB expiration date is not inappropriate.

A.18 Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.