Red Carpet Entry (RCE) Program Implementation Project

OMB No. 0920-New

February 18, 2022

Supporting Statement

Part A

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EXHIBITS

LIST OF ATTACHMENTS

Goal of the project: To create a toolkit for HIV clinics to implement the Red Carpet Entry (RCE) Program and test the toolkit in two clinics.
Intended use of the resulting data: To share the RCE implementation toolkit and study findings with HIV care clinics so they can use the program to link new patients to care.
Methods to be used to collect data: The only data HIV patients need to provide will come from their electronic health record about their appointments and lab results. Clinic staff implementing RCE will be interviewed and will take online surveys about their experiences with the program and using the toolkit.
The subpopulation to be studied: Persons newly diagnosed with HIV or who are returning to care at the participating clinics.
How the data will be analyzed: Statistical analysis of survey data and the effect of RCE on percentage of persons who are linked to and retained in care. Thematical and/or framework analysis of interviews to provide context for why the program works or fails and to identify any issues with the toolkit. Labor and non-labor costs will be evaluated using a micro-costing approach.

Supporting Statement

A. Justification

1. **Circumstances Making the Collection of Information Necessary**

The Centers for Disease Control and Prevention's (CDC) Division of HIV Prevention, (DHP) requests OMB approval for 24 months of data collection for a research study titled, "**Red Carpet Entry (RCE) Program Implementation Project**" as a new information collection.

Whitman Walker Health and the District of Columbia (DC) Department of Health's HIV/AIDS, Hepatitis, STD, and TB Administration developed and implemented the Red Carpet Entry Program (RCE) in August 2009 to make sure that people testing HIV-positive or returning to HIV care get fast-tracked to see an HIV provider or care team within the first three days. RCE focuses on engaging patients by treating them like VIPs and reduce patient burden by making many of the initial processes new patients have to go through easier on them. An evaluation of RCE found that 70% of newly diagnosed persons with HIV (PWH) were linked to care within 72 hours (Olejemeh et al., 2012). The scientific literature shows us that PWH who are linked to care within one month of diagnosis have significantly higher rates of viral suppression (less HIV in their bodies) and take less time to achieve viral suppression than PWH who are linked to care within two to three months of diagnosis (which is the average amount of time to get an appointment) (Hall et al., 2016). An adapted version of RCE has also been shown to improve outcomes among adolescents and youths in Kenya (Ruria et al., 2017). The school-based RCE program increased rates of linkage to care for PWH in the first three days from 56.5% to 97.3%

and increased the likelihood of PWH coming back for a second visit at 3-months from 66.0% to 90.0% (Ruria et al., 2017). Based on this evidence, the CDC identified RCE as an *evidence-informed intervention* (EBI) in the Compendium of Evidence-based Interventions and Best Practices for HIV Prevention (Centers for Disease Control and Prevention, 2019). Because there are so few structural interventions that increase the speed at which PWH get into care, the CDC is interested in making RCE available for other clinics and HIV providers to use.

Having an evidence-informed intervention like RCE that can be disseminated to the broader HIV health care community is important because: (1) it gets PWH into effective treatments, such as anti-retroviral therapy (ART), which is the best way to manage HIV; (2) by treating patients like VIPs, it encourages them to come back, which makes PWH more likely to stay in care and benefit from long term treatment, and (3) it increases the number of evidence-informed structural interventions available to HIV care providers. The practical significance of this research is the implementation toolkit that will be developed and evaluated as well as the experiences of the study clinics in putting RCE into practice. Effective implementation strategies and toolkits are needed to make evidence-based programs easier to adopt. Therefore, the study will evaluate the RCE toolkit to make sure it can be used easily, that the program runs properly, and that PWH are connected to a provider or care team within three days. The study will evaluate key components that contribute to program effectiveness according to implementation science, including the implementation strategies used to prepare for and implement RCE, adaptations made to integrate RCE, implementation context, and implementation outcomes such as acceptability, appropriateness, feasibility, fidelity, reach, and sustainability. Based on the information collected in this study, the toolkit will be revised to include experiences of the clinics and their implementation strategies and adaptations. The RCE toolkit will be disseminated by CDC to the broader HIV health care community. This is important because only federal agencies like CDC have the resources and infrastructure to broadly disseminate EBIs. Broad dissemination and uptake of EBIs like RCE can help lower population rates of HIV transmission.

This request is authorized by Title III – General Powers and Duties of the Public Health Service, Section 301 (241.) a. Research and investigations generally (**Attachment 1**).

2. Purpose and Use of Information Collection

The purpose of the RCE Program Implementation Project is to create and evaluate a toolkit for HIV clinics to implement RCE, a structural evidence-informed intervention to improve linkage to care. The toolkit will be tested in two clinics, Rutgers New Jersey Medical School Infectious Disease Practice (referred to as Rutgers) and the Hillsborough County Health Department in Florida (referred to as Hillsborough). Toolkit materials will be developed with the assistance of the original developers at Whitman Walker Health and the District of Columbia Department of Health as well as a Community Advisory Board.

This study aims to understand the process of implementing RCE in clinics, including strategies used, adaptations made, and barriers and facilitators encountered; evaluate the implementation context and implementation outcomes; assess the costs of implementing RCE; evaluate whether RCE improves how long it takes to link PWH to care and stay in care compared with PWH linkage to and retention in care experiences at the clinics before the study; and test the toolkit

materials. Data will be collected via surveys, interviews, and questionnaires with clinic staff and leadership implementing RCE and will be abstracted from medical records for RCE clients. This study will address these aims using (1) quantitative surveys and qualitative semi-structured interviews administered over seven timepoints to identify the implementation strategies used and adaptations made to RCE to integrate the program into the clinic context, (2) quantitative surveys and qualitative semi-structured interviews administered over seven timepoints to reveal how implementation outcomes and the context in which RCE is implemented changes over time, (3) labor and non-labor cost questionnaires administered once during the pre-implementation phase and every 1-2 months during the implementation phase to estimate the cost of implementing RCE, (4) quantitative surveys and qualitative semi-structured interviews with staff to evaluate and provide feedback on materials testing of the toolkit components every two months with each assessment focusing on different component(s) of the toolkit (i.e., orientation video, training videos, readiness checklist, implementation manual, quick guide, marketing materials, and the report card; see **Attachment 8**), and (5) extract appointment, demographic, and date of diagnosis data from patient medical records to assess the impact of RCE on linkage to care (primary) and retention in care (secondary) outcomes. Data collection will continue for an additional two months after implementation to assess retention in care outcomes (i.e., whether patients make a second appointment with their provider, whether viral load values improve). Each clinic will take 3-months to prepare for implementing RCE (i.e., receive training and technical assistance), will implement RCE for six months, and will collect data for an additional two months to assess retention in care. Clinic staff will participate in five data collection activities each in total. PWH enrolled in RCE will not participate directly in any data collection activities. All data related to PHW will be extracted from the clinic's electronic health records. The overall study timeline, including data collection and analysis, is shown in Exhibit A16.1.

A total of ten clinic staff (four implementing staff members and one person in clinic leadership from each of the two clinics) and a total of 126 clients will result in a total of 136 participants. Data collectors will be trained on all study procedures.

Exhibit A2.1 Items of Information to be Collected

Variables to be explored	**Data collection tool and citation**	**Study Related Procedures**	**Target Population**
Eligibility criteria for RCE Clients: newly diagnosed or new to care/out of care, consent to share their appointment, demographics, date of diagnosis, ability to speak English or Spanish.	RCE Clients: Attachment 3j. Screener	Short eligibility screener	Newly diagnosed/returning to care HIV+ persons able to be seen for care at an implementing clinic (RCE Clients)

Program implementation process in clinical sites, including implementation strategies used, adaptations made, and barriers and facilitators encountered; implementation context and outcomes; materials testing of the toolkit components	Attachment 3a, 3b, & 3c. Staff Survey	Online self-administered survey	Implementing Clinic and referral partner Staff (the clinical champion, RCE concierge, and two CTR counselors per implementing clinic)
Program implementation process in clinical sites; implementation context and outcomes; materials testing of the toolkit components	Attachment 3d. Staff Interview Guide – Preparation Phase	Semi-structured in-person interviews	Implementing Clinic and referral partner Staff
Program implementation process in clinical sites; implementation context and outcomes; materials testing of the toolkit components	Attachment 3e. & 3f. Staff Interview Guide –Implementation Phase	Semi-structured in-person interviews	Implementing Clinic and referral partner Staff
Program Non-Labor cost data	Attachment 3i. Non-Labor Cost Questionnaire	Excel workbook for entering costs	Implementing Clinic and referral partner Staff
Program Labor cost data	Attachment 3h. Labor Cost Questionnaire	Excel workbook for entering costs	Implementing Clinic and referral partner Staff
Program implementation process in clinical sites; implementation context and outcomes	Attachment 3g. Clinic Leadership Interview Guide	Semi-structured in-person interviews	Implementing Clinic Leadership
Program implementation process in clinical sites; implementation context and outcomes	Attachment 8c. RCE Report Card	Word document for reporting implementation progress	Implementing Clinic Staff

3. Use of Improved Information Technology and Burden Reduction

Variables of interest for this project will be explored in online surveys and face-to-face interviews. Staff surveys (attachments 3a, 3b, and 3c) will be online, self-administered surveys

accounting for 11.2% of the data collection activity. Online surveys are short (15 minute) repeated surveys and online administration reduces any additional burden acquired via face to face interaction for data collection. Interviews will be conducted in-person. Telephone interviews or virtual interviews (such as via Zoom or Skype) are not optimal for developing the necessary rapport between interviewer/facilitator and respondent(s) for a successful interview. Body language and facial cues are critical to understand where additional probing may be needed or should stop, and telephone or virtual interviews limit the interviewer's ability to assess both. In addition, telephone and virtual interviews more often lack the controls necessary to minimize ambient sounds, as well as intrusions to the interview process. Thus, we will conduct individual, semi-structured interviews in person, unless COVID-19 pandemic containment is required, in which case we will use a virtual platform. After receiving permission from respondent(s), we will digitally audio-record the interview (this is also possible using virtual platforms). Recordings will be transcribed as soon as possible after the interview. Audio-recording limits the burden on the respondent and allows the interviewer to focus on building and maintaining rapport with the respondent, as well as ensuring the completeness of responses during transcription. Implementation staff and clinic leadership interviews will be led by an interviewer and a note-taker will be present. The role of the note-taker is to allow the interview to flow with limited interruption.

4. Efforts to Identify Duplication and Use of Similar Information

This collection of data will involve gathering key information that the Agency believes is not captured elsewhere. The Agency believes no other data collection effort in the United States has been conducted or has been planned to collect information about RCE. CDC conducted a review of similar studies prior to the issuance of the contract and determined that this study is collecting unique information about RCE. Although RCE has been adapted and implemented broadly in international settings, it has not been implemented broadly in the U.S. There is very little data on implementation of RCE outside of the District of Columbia. Therefore, our evaluation requires the collection of this new primary data. There would be no reason for another Federal Agency to evaluate this.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be impacted by this study. We will partner with clinic sites and their referral partners (Community Based Organizations) to aid in referring potential respondents by providing them with RCE marketing materials.

6. Consequences of Collecting the Information Less Frequently

The present study will provide the primary qualitative and quantitative data needed to assess the successful implementation in two HIV clinics of the RCE. If this evaluation were not conducted, it would not be possible to understand the process, context, and costs of implementing RCE in clinical sites; measure potential improvement in clients' linkage to and retention in care rates compared with baseline; and conduct materials testing of the toolkit components. Each clinic will prepare for RCE implementation for three months and then implement RCE.

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

This data collection effort does not involve any special circumstances.

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

A 60-day notice to solicit public comments was published in the Federal Register Friday, August 20, 2021, Vol. 86, No. 159, Page Number 46852 (**Attachment 2**). One public comment was received (**Attachment 2a**). The comment was in support of the project and recommended CDC expand the number of initial sites. CDC responded directly to the commenter but did not change the information collection as a result of the suggestions.

Consultants for the study include Research Triangle Institute (RTI) staff, RCE experts from Whitman Walker Health and DC Department of Health, and an Implementation Science expert (Byron Powell). Aside from the official public comment periods in the Federal Register, there were no other public contacts or opportunities for public comment on this study.

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9. Explanation of any Payment or Gift to Respondents

Each consenting RCE client will receive a one-time token of appreciation of $25. Gift cards will be provided to clients as appreciation for allowing access to their Electronic Health Record (EHR) data, and the amount has been selected to be non-coercive. Although there has been some

debate on the necessity of offering tokens of appreciation, numerous studies have shown that tokens of appreciation can significantly increase response rates and the use of modest tokens of appreciation is expected to enhance response rates without bias (Abreu & Winters, 1999; Shettle & Mooney, 1999). Enrolling enough PWH into this study in a 6-month period and accessing their EHR data is essential for understanding whether RCE was implemented with fidelity and expected health outcomes achieved (being linked to care in 72 hours, returning for a second appointment, reduced viral load).

Clinic staff and leadership will not receive a token of appreciation as data collection occur as part of their employment activities.

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

This submission has been assessed for applicability of 5 U.S.C. § 552a and it has been determined that the Privacy Act is not applicable as no personally identifiable information (PII) is being collected by a direct identifier for transmission to the CDC. A privacy impact assessment (PIA) has been conducted and approved (**Attachment 9**).

The Contractor will be responsible for collecting all data for this study. To ensure that respondents' health information is protected, we will take the following measures to separate PII from study-related data: (1) all respondents will receive unique identification codes, which will be stored separately from PII on a password protected computer and or locked file cabinet; data will be collected by trained study staff using a secure, password-protected database stored on the participating clinic's secure server or project computer; and (2) we will train researchers who play a role in data collection and analysis in proper procedures for securing project data and protecting participant confidentiality. We will inform respondents that their responses will be kept private to the extent permitted by the law. All respondents will be informed that the information collected will not be attributable directly to the respondent. Terms of the CDC contract authorizing data collection require the Contractor to maintain the privacy of all information collected.

Online survey data will be collected and managed using Qualtrics©. Medical records data for consenting clients will be accessed by the data manager at each clinic to extract appointment attendance data from the clinic's EHR and enter the data into a secure, password-protected database stored on the clinic's server or project computer. `Transcripts of interviews and focus groups will be stripped of identifiers. No PII will be included in the transcriptions. If the respondent divulges PII during the interview, the transcriber will convert the PII to bracketed non-PII descriptor information (i.e., [Provider's Name]). No names or identifiers will be used when transcribing the data.

When not in use, all completed hardcopy documents will be stored in locked file cabinets or locked storage rooms. All project related documents and audio recordings will be destroyed when no longer needed for the project.

Qualtrics was selected as the data collection platform for the quantitative surveys because of the anti-hacking measures, firewalls, and constant security scans, the parent company completes on behalf of subscribers.

The NCHHSTP IT Security Information System Security Officer (ISSO) determined that a System Assessment and Authentication (SA&A) package, and Enterprise Performance LifeCycle (EPLC) sequence were not needed for this data collection.

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

IRB

The study protocol was reviewed and approved by Research Triangle Institute International's IRB in March 2021 and amended and approved in June 2021 (**Attachment 5a**).

Sensitive Questions

This study will collect sensitive information about HIV diagnosis and viral load through abstraction of medical records only. No sensitive questions are asked.

12. Estimates of Annualized Burden Hours and Costs

12A. Estimated Annualized Burden Hours

RCE Clients. Each clinic has two referral partners, an internal clinic within their hospital system and an external community-based organization that conducts HIV testing. Newly diagnosed and out-of-care PWH will be recruited into the RCE Program through the clinics' networks of referral partners and via social media advertisements. Referral partners will provide clients with palm cards. We anticipate screening a total of 180 respondents and anticipate the screening process to take 5 minutes per respondent for a total of 15 burden hours (**Attachment 3j)**. Of the 180 respondents screened, we anticipate a 66% response rate.

RCE Staff. Clinic staff and leaders will be trained in RCE implementation, marketing, and promotion. We expect a 100% response rate at each clinic.

These numbers were estimated by the contractor RTI based on respondents' time to complete similar surveys from a similar project, Positive Health Check (PHC) [OMB Control No. 0920-1211]. RCE implementation staff and system stakeholders will participate in data collection activities. RCE Clients will not participate directly in any data collection activities. All data related to RCE Clients will be extracted from the clinics' EHR systems or collected by the RCE Concierges as part of routine program activities.

Exhibit A12.1: Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
RCE Clients	Attachment 3j. Screener	180	1	5/60	15
RCE Implementation Staff	Attachment 3a, Staff Survey – Preparation Phase	8	1	15/60	2
RCE Implementation Staff	Attachment 3b. Staff Survey - Implementation Phase (months 1,3,5)	8	3	15/60	6
RCE Implementation Staff	Attachment 3c. Staff Survey - Implementation Phase (months 2,4,6)	8	3	15/60	6
RCE Implementation Staff	Attachment 3d. Staff Interview Guide – Preparation Phase	8	1	1	8
RCE Implementation Staff	Attachment 3e. Staff Interview Guide – Implementation Phase (months 1,3,5)	8	3	30/60	12
RCE Implementation Staff	Attachment 3f. Staff Interview Guide – Implementation Phase (mos 2,4,6)	8	3	30/60	12
Clinic Leadership	Attachment 3g. Clinic Leadership Interview Guide	2	1	30/60	1

Type of Respondents	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
RCE Implementation Staff	Attachment 3h. Labor Cost Questionnaire	6	4	1.5	36
RCE Implementation Staff	Attachment 3i. Non-Labor Cost Questionnaire	2	9	1.5	27
RCE Implementation Staff	Attachment 8c. RCE Report Card	2	3	15/60	2
Total					**127**

12B. Estimated Annualized Burden Costs

The annualized costs to the respondents are described in Exhibit A12.B. The United States Department of Labor Statistics, May 2020 http://www.bls.gov/oes/current/oes_nat.htm was used to estimate the hourly wage rate for the general public and clinic managers for the purpose of this request. This cost represents the total burden hours to respondents multiplied by the average hourly wage rate for general public adults ($27.07) and clinic managers ($57.12). Annualized burden costs are $3,467.94.

Exhibit A12.2. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public-Adults	Attachment 3j. Screener	15	$27.07	$406.05
General Public-Adults	Attachment 3a. Staff Survey Preparation Phase	2	$27.07	$54.14
General Public - Adults	Attachment 3b. Staff Survey (months 1,3,5)	6	$27.07	$162.42
General Public - Adults	Attachment 3c. Staff Survey (months 2,4,6)	6	$27.07	$162.42

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public - Adults	Attachment 3d. Staff Interview Guide – Preparation Phase	8	$27.07	$216.56
General Public - Adults	Attachment 3e. Staff Interview Guide – Implementation Phase (months 1,3,5)	12	$27.07	$324.84
General Public - Adults	Attachment 3f. Staff Interview Guide – Implementation Phase (months 2,4,6)	12	$27.07	$324.84
Clinic Managers	Attachment 3g. Clinic Leadership Interview Guide	1	$57.12	$57.12
General Public- Adults	Attachment 3h. Labor Cost Questionnaire	36	$27.07	$974.52
General Public - Adults	Attachment 3i. Non-Labor Cost Questionnaire	27	$27.07	$730.89
General Public - Adults	Attachment 8c. RCE Report Card	2	$27.07	$54.14
Total				**$3,467.94**

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

There are no costs to respondents for participating in this survey.

14. Annualized Cost to the Government

The annualized cost to the government is $662,634.00.

Exhibit A14.1: Annualized Cost to the Government

Expense Type	Expense Explanation	Annual cost
Direct Cost to Government	Contract Cost: Research Triangle Institute	$589,502
	CDC, Technical Monitor (GS-14, 0.20 FTE)	$27,532
	CDC, Consultant (GS-14, 0.10 FTE)	$14,530
	CDC, COR (GS-13, 0.10 FTE)	$12,620
	CDC Contract Support: SeKON, Project Coordinator	$18,450
	ANNUALIZED COST	**$662,634**

The annualized cost to the government is $662,634. The information collection described in this request will be funded, coordinated, and managed through a contract with the contractor, Research Triangle Institute (RTI). The federal personnel involved in the project include a Technical Monitor at the GS 14 equivalent level, a CDC consultant at the GS 14 level, and a CDC Contracting Officer Representative at the GS 13 level. Additional staffing comes from a CDC support contract with SeKON for a Project Coordinator.

Federal salaries were obtained from the US Office of Personnel Management salary scale at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2021/ATL.pdf

15. Explanation for Program Changes or Adjustments

This is a new data/information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

RTI will provide a final report to CDC describing the results of this study and update the RCE toolkit according to these findings. CDC will disseminate the updated toolkit to local and state health departments and other interested parties to enhance HIV care linkage and re-engagement to meet HHS's *Ending the HIV Epidemic* goals. The project timeline is detailed in exhibit A16.1.

Exhibit A16.1: Project Time Schedule

Activity	
Contractor and intervention implementation staff training	1 month before to 1 month after OMB approval
Data Collection	3-11 months after OMB approval
Toolkit finalized, data analysis finalized, and reports drafted	12-23 months after OMB approval
Final toolkit, data and reports submitted to CDC	24 months after OMB approval

We anticipate that the Toolkit will be made available on CDCs website, https://www.cdc.gov/hiv/effective-interventions/index.html. Publications will be developed to share lessons learned about implementation and RCE outcomes. Manuscripts will be published in peer reviewed journals, presented at national conferences, and provided on conference websites. Links to these publications will be available through the CDC website. In addition, per CDC guidelines, demographic and text data will be publicly available by special use request after study completion and dissemination of findings.

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

REFERENCES

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