

Impact of Representative Payee Services on ART Adherence among Marginalized People Living with HIV/AIDS

Principal Investigator: Mary Hawk

**Funded by: National Institutes of Health
National Institute of Mental Health**

1 R01 MH112416-01A1

Version Number V.3

20 July 2018

CONTENTS

List of Abbreviations.....	3
Statement of Compliance	4
Protocol Summary	5
STUDY PROTOCOL.....	8
1.0 Research Team	8
2.0 Background.....	10
3.0 Approach	12
3.1 Innovation	12
3.2 Hypotheses and Aims	13
3.3 Study Design Rationale.....	13
4.0 Potential Risks and Benefits.....	14
4.1 Risks to Human Subjects	14
4.1.1 Sources of Materials	15
4.1.2 Potential Risks.....	15
4.2 Adequacy of Protection against Risks	15
4.2.1 Patient Recruitment and Informed Consent.....	15
4.2.2 Protections against Risk.....	16
4.3. Potential Benefits of the Proposed Research to Human Subjects	17
4.3.1 Importance of the Knowledge to be Gained.....	17
5.0 Subject Selection and Recruitment	17
5.1 Inclusion/Exclusion Criteria	17
5.1.1 CCRP Inclusion Criteria.....	17
5.1.2 CCRP Exclusion Criteria	18
5.2 Qualitative Interviews	18
5.2.1 CCRP Participants.....	18
5.2.2 Providers	18
5.3 Subject Recruitment.....	18
5.3.1 Screening	19
5.3.2 Consent.....	19
5.3.3 Retention	20
5.4 Incentives	20
5.5 Study Participation	20
5.5.1 Study Withdrawal	20
5.5.2 Study Termination	20
5.5.3 Voluntary Nature of Participation.....	20
5.5.4 Assignment of Rep Payee.....	21
5.5.5 Withdrawal from Rep Payee	21
6.0 Study Procedures.....	21
6.1 Randomization	21
6.2 Data Collection	22
6.2.1 Cost, Cost Threshold, and Cost-Utility Analyses	24
7.0 CCRP	24
8.0 Data and Safety Monitoring Plan	25
8.1. Summary of the Protocol	25
8.2 Roles and Responsibilities	26

8.3 Trial Safety.....	26
8.4 Adverse Events, Serious Adverse Events, and Unanticipated Problems	27
8.5 Reporting Policy and Timeframe	28
8.6 Data Management	28
9.0 Statistical and Analytical Plan	31
9.1 Approach	31
9.2 Objectives and Primary Comparisons	31
9.2.1 Sample Size and Power Calculations.....	32
9.3 Semi-Structured Qualitative Interviews	32
9.4 Economic Analysis	33
10.0 Quality Assurance and Quality Control	35
10.1 Study Oversight	35
10.2 Staff Training	35
10.2.1 CCRP Fidelity	35
10.2.2 Visits to Site	36
11.0 Conflict of Interest	36
APPENDICES	37
Appendix A. Data Security Assessment Form.....	37
Appendix B. Participant Consent	42
Appendix C. Action Wellness Notice of Privacy Practices	50
Appendix D. Script for Participation: Provider Qualitative Interviews	60
Appendix E. Semi-Structured Interview Protocol (Drafts)	61
Participant Protocol	61
Provider Protocol	63
Appendix F. University of Pittsburgh IRB Approval Letter	64
Appendix G. Philadelphia Health Department IRB Approval Letter	65
Appendix H. DSMB Forms.....	67
CCRP Adverse Events Form	67
CCRP Serious Adverse Events Form	69
CCRP Unanticipated Problem Form	71
Data Safety Monitoring Minutes Template.....	73
REFERENCES.....	74

TABLE OF FIGURES

Figure 1. Schematic of Study Design	6
Figure 2. CCRP Theorized Mechanisms of Change	7
Figure 3. Adverse Events Flowchart	30

TABLE OF TABLES

Table 1. Enrollment Targets.....	19
Table 2. Key Study Variables with Measurement Tools and Data Collection Points.....	22
Table 3. Sample Size Required to Detect Specified Effects	32
Table 4. Visits to Clinical Site	36

List of Abbreviations

ART	Antiretroviral Therapy
CCRP	Client Centered Representative Payee
DSMB	Data and Safety Monitoring Board
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
PLWHA	People Living with HIV/AIDS
RCT	Randomized Controlled Trial
SES	Socioeconomic Status
SSA	Social Security Administration
SSDI	Social Security Disability Insurance
SSI	Supplemental Security Income

Statement of Compliance

The trial will be conducted in accordance with the ICH E6, the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), and the NIH/NIMH Terms of Award. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

I agree to ensure that all staff members involved in the conduct of this study are informed about their obligations in meeting the above commitments.

Mary E. Hawk

Principal Investigator



Signature

February 27, 2017

Date

Protocol Summary

Title: Impact of Representative Payee Services on ART Adherence among Marginalized People Living with HIV/AIDS

Précis: This randomized controlled trial (RCT) will test the impact of Client-Centered Representative Payee (CCRP) services on marginalized people living with HIV/AIDS. The primary research center is the University of Pittsburgh and the study site is Action Wellness. An economic analysis will be conducted by researchers at Johns Hopkins University Bloomberg School of Public Health.

We hypothesize that by helping clients to pay their rent and other bills on time, housing stability will improve and financial stress will decrease. Financial management will occur via a policy of the Social Security Administration referred to as Representative Payee, which enables a person or organization to manage bills and entitlements on behalf of an individual with need. By reducing the cognitive burden of living with chronic financial stress and frequent threats of housing loss, clients will be able to devote more time to medical appointments and medication adherence. Ultimately, we believe that this program will improve clients' self-efficacy for health behaviors, retention in care, medication adherence, CD4 counts, and viral loads.

Participants (n=320) will be randomized to the intervention or the standard of care. Participants in the intervention arm will receive CCRP services for a period of 12 months. We will collect clinical and self-report data for participants in both arms and use mixed methods to explore underlying mechanisms contributing to changes in adherence and viral suppression rates. Self-assessment data will be collected at baseline, 3-month, 6-month, and 12-month time points and will incorporate the following primary domains: ART adherence, housing instability, self-efficacy for health behaviors, financial stress, and retention in care. Mini check-ins will occur at 1- and 9-month time points. Viral load, CD4, and appointment adherence data will be collected at baseline, 6 months, 12 months, 18 months, and 24 months via abstraction from Action Wellness patient records. Mixed methods will be used to test our hypotheses, including a mediation analysis, process measures, survey measures, and qualitative interviews with participants. Qualitative interviews will also be conducted with 15 providers to explore factors perceived by providers to contribute to ART adherence. Finally, we will conduct an economic evaluation to assess the cost, cost threshold, and costutility of the CCRP model.

Study Period: May 2017 –April 2022

Active Participant Duration: 12 months plus 12 additional months of clinical monitoring

Population: People living with HIV/AIDS who are 18 years of age and older, English- or Spanish-speaking, recipient of Social Security entitlements (SSI and/or SSDI), not currently receiving representative payee services nor having received them in the past 12 months, income below 138% of the federal poverty level, and one or more of the following: not virally suppressed, unsustained viral suppression over the past 12 months, or poor ART adherence.

Figure 1. Schematic of Study Design

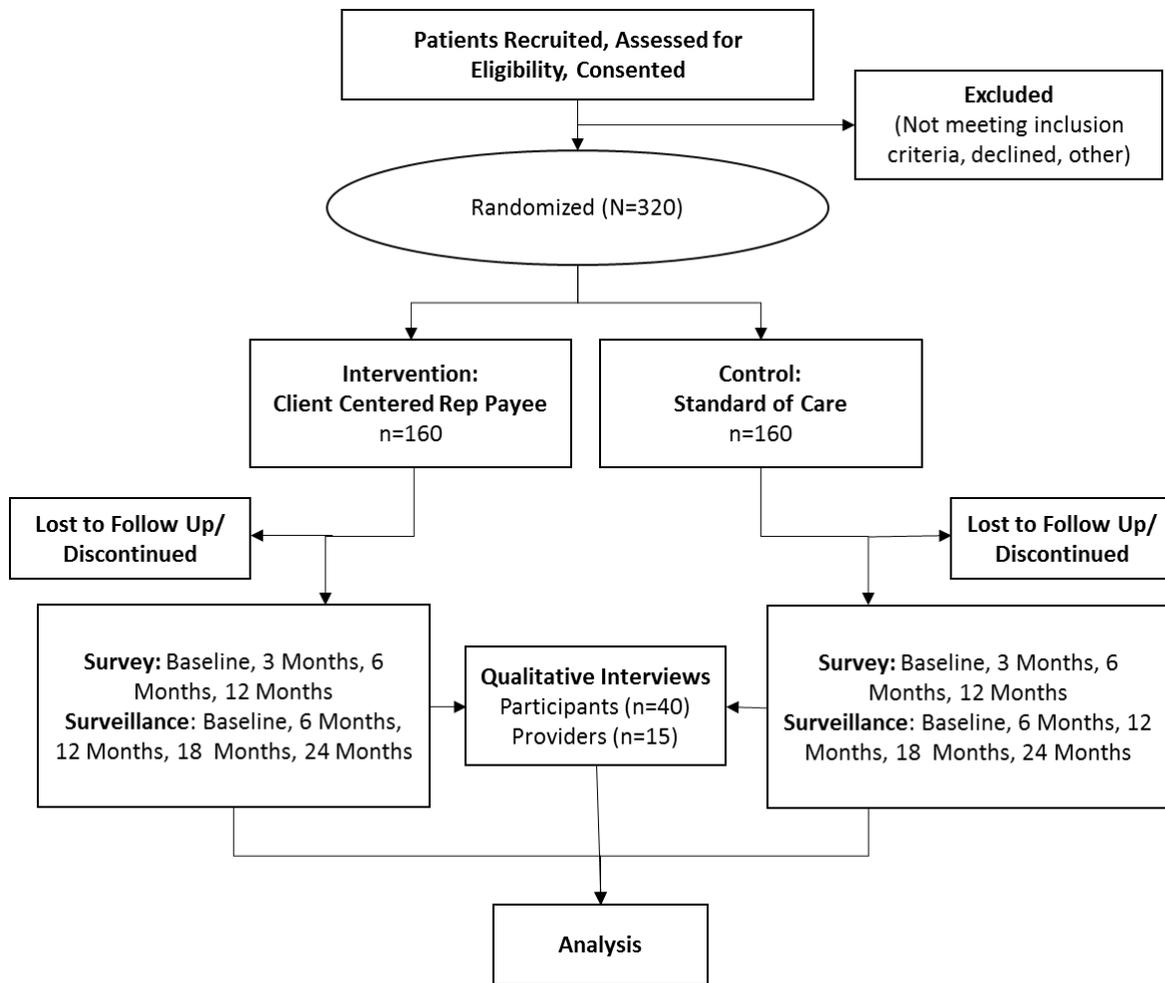
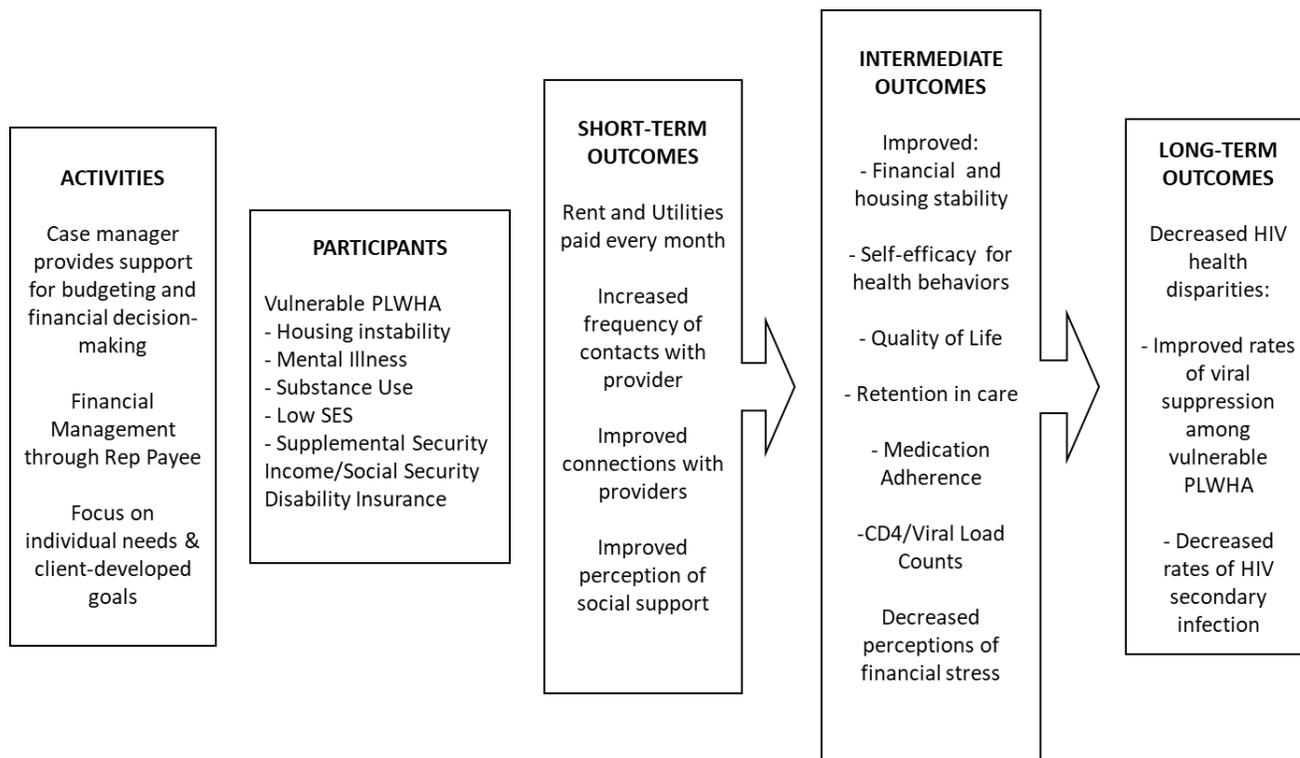


Figure 2. CCRP Theorized Mechanisms of Change



STUDY PROTOCOL

1.0 Research Team

Principal Investigator

Mary Hawk, DrPH
Assistant Professor
Co-Director, Evaluation Institute for Public Health
University of Pittsburgh Graduate School of Public Health
4136 Parran Hall
130 DeSoto Street
Pittsburgh, PA 15261
meh96@pitt.edu
412.648.2342

Co- Investigators

Ron Stall, PhD
Professor, Behavioral and Community Health
Sciences
Professor, Infectious Diseases and Microbiology
Director, Center for LGBT Health Research
University of Pittsburgh Graduate School of
Public Health
4139 Parran Hall
130 DeSoto Street
Pittsburgh, PA 15261
rstall@pitt.edu
412.624.7933

Maria Mori Brooks, PhD
Professor and Vice Chair of Education,
Epidemiology
Co-Director, Epidemiology Data Center
Professor, Biostatistics
University of Pittsburgh Graduate School of
Public Health
A530 Crabtree Hall
130 DeSoto Street
Pittsburgh, PA 15261
mbrooks@pitt.edu
412.624.1618

Elizabeth Hagan, MEd
Deputy Executive Director
Action Wellness
1216 Arch Street, 6th Floor
Philadelphia, PA 19107
215-981-3359
Fax: 215-558-6617
BHagan@actionwellness.org

David R. Holtgrave, PhD
Professor and Chair, Department of Health,
Behavior, and Society
624 N. Broadway
Hampton House 280B
Baltimore, Maryland 21205
david.r.holtgrave@jhu.edu
410.502.4076

Catherine Mulsby, PhD
Associate Scientist
624 N. Broadway
Hampton House 904C
Baltimore, Maryland 21205
cmulsb1@jhu.edu
410-614-3454

Content Experts

Dana Davis, PhD
Assistant Professor
Youngstown State University
School of Social Work
Cushwa Hall 3379
One University Plaza
Youngstown, OH 44555
ddavis05@ysu.edu
330.941.2056

Christina Farmartino, MPH
Executive Director
The Open Door, Inc.
PO Box 99243
Pittsburgh, PA 15233
cfarmartino@opendoorhousing.org
412.977.7973

2.0 Background

Economic disadvantage can serve as a barrier to optimizing ART adherence, driving health disparities and the HIV epidemic. Numerous studies have shown the association between financial strain and poor health outcomes including impaired functional status (1), serious health conditions (2), and all-cause mortality (3). These associations are magnified within the HIV epidemic. Low socioeconomic resources are associated with poor engagement in care and failed viral suppression (4). Homelessness has been shown to exacerbate both HIV transmission and progression to AIDS (5). Housing instability is also correlated with lower rates of engagement in care and treatment adherence among PLWHA (6). Individuals with low socioeconomic status (SES) have higher rates of substance use and mental health issues (7-11), which have reciprocal relationships with low SES, and each of these factors is correlated with HIV health disparities (12-16). Individuals with low SES also have higher rates of housing instability. These factors create a syndemic (17) that produces higher rates of HIV infection; poorer engagement, retention, and adherence to care; and higher risk of negative outcomes including death.

Interventions to improve antiretroviral therapy (ART) adherence have demonstrated gains, but critical gaps remain as indicated by continuously low rates of viral suppression and unrelenting cases of new transmissions. A recent systematic review of 126 interventions to improve ART adherence noted that there are gaps in the evidence of these adherence interventions with regards to cost-effectiveness, long-term effectiveness, and effectiveness within specific populations (18).

Further, there is a lack of structural interventions to improve ART adherence, which represents missed opportunities to reduce HIV health disparities. Structural interventions aim to alter social, political, or economic contexts in order to improve public health (19, 20). Rather than focusing on these fundamental issues, most interventions seeking to improve ART adherence and rates of viral suppression work on behavioral levels, placing the burden on the individual to create change. However, behavioral changes are greatly influenced by cultural and socioeconomic factors and are therefore highly variable (18). Few published studies have examined the impact of structural interventions on ART adherence. In the previously cited systematic review, only 10 of 126 interventions focused on structural approaches, and these intervened primarily by changing the provider giving ART to the patient or the location where ART was provided. Of those 10 studies, only 1 demonstrated significant effects on both biologic and subjective or objective adherence outcomes (18). Because structural interventions seek to change the context in which health is produced (19) they present the best potential for broader reach and durability of effects.

Structural interventions to improve HIV outcomes are clearly needed, and these must seek to improve ART adherence by altering the effects of economic disadvantage. Research in this area so far is limited. Some studies have suggested that monetary incentives for HIV testing, retention in care (21), and ART adherence (22) may be effective; however, little is known about the long-term durability and effectiveness of these interventions, which may require incentives to continue indefinitely and do not address underlying socioeconomic factors. Research outside of the field of HIV has described two pathways between low SES and poor health outcomes: neo-materialism and biopsychosocial pathways (3). The former describes the impact of limited resources, such as food, housing, and access to care, on sub-optimal health behaviors and ultimately health outcomes (23), while the latter describes stressors resulting from financial strain, which directly impact health outcomes (2). The cumulative load of financial stress has been shown to have a long-term effect on health (2), and poverty has been shown to directly impede cognitive function by reducing the availability of mental resources for other tasks (24). The concept of Competing Neurobehavioral Decision Systems describes the process in which long-term, healthy behavioral decision-making is co-opted by the experience of financial strain, which requires a high burden of mental processes to juggle demands and make financial tradeoffs (24). Thus, future studies of adherence improvement interventions targeted to PLWHA who have low SES should test the degree to which they not only help clients stabilize resources but also ease their perceptions of stress associated with chronic financial crises.

Client-Centered Rep Payee is a structural intervention that may mitigate the effects of economic disadvantage to improve housing and financial stability, enabling self-efficacy for health outcomes and improved ART adherence. Client-Centered Rep Payee (CCRP) helps clients to consistently pay their bills including rents and utilities. By making these necessary payments, which often cause stress for people with low SES, clients can focus on other aspects of their lives

including increasing ART adherence. CCRP may redirect the expenditure of participants' resources toward improved health behaviors. Shifting the focus of material and biopsychosocial resources may change the context in which health behaviors are produced, contributing to higher rates of adherence and viral suppression.

CCRP modifies the implementation of a current policy of the Social Security Administration (SSA) to create an intervention that is highly replicable. Representative payee services have been shown to decrease homelessness and money mismanagement and to improve quality of life among people with mental health or substance use disorders (25). In some settings, representative payee has been provided to individuals with serious mental illness specifically to enforce appointment adherence, with the idea that if clients must visit the provider to gain access to funds, they will also gain access to clinical care (26). However, this approach has also been associated with clients' experiences of coercion and reduced autonomy (27). Our CCRP model modifies implementation of the traditional representative payee approach by emphasizing client decision-making and goal-setting while providing financial management services through the long-standing SSA policy. Emphasizing client autonomy is an important addition to traditional representative payee services, because these approaches engender trust and strengthen the relationship between the client and the provider, improving retention in care (28-30).

This intervention is targeted to vulnerable individuals who receive public entitlements, including Supplemental Security Income (SSI) and Social Security Disability Insurance (SSDI), both of which fund basic needs for people with disabilities. Eligibility status for SSI includes US citizens who are aged, blind, and/or disabled, and who have very limited income and financial resources. SSDI has similar eligibility requirements; the main difference between the two is that people who receive SSDI have worked for a number of years and have made contributions to the Social Security Trust fund.

CCRP can be embedded within existing services in HIV clinical settings and will include medical case managers and financial managers. Medical case managers refer clients to CCRP. Each client completes a request to SSA to appoint the Rep Payee prior to initiation of financial management services, and SSA authorization typically occurs within 3 months. Clients may terminate the representative payee appointment at any time by submitting a form to SSA. The medical case manager helps the client to create a budget and prioritize expenditures, focusing on housing and utilities in order to enhance housing stability. The medical case manager therefore becomes the point-person for the CCRP service. Money management is provided by a representative payee financial manager who sets up a bank account on behalf of the client. Once the SSA authorizes the organizational payee, Social Security entitlements (SSI and/or SSDI) are sent directly to that account. Checks or electronic transfers are paid by the financial manager directly to the billers, including landlords and utility companies. The financial manager is not identified to the client, which not only is a safety precaution but also helps to ensure that discussions about budgeting and practical needs become part of the ongoing conversation between the client and the case manager.

Pilot data suggest that providing CCRP to PLWHA who have low SES is feasible, acceptable to the clients, and effective in improving viral suppression. In the past nine years, 76 homeless and unstably housed PLWHA have received these services through a transitional housing program called The Open Door (TOD). TOD is a nonprofit organization established in Pittsburgh, PA in 2006, to improve clinical outcomes for homeless people living with HIV/AIDS. The organization uses a housing first model of care to stabilize PLWHA who are chronically homeless and prioritizes services for individuals who are likely to be poorly retained in traditional care services, including people with serious mental illness, substance use disorders, and criminal histories. Housing first prioritizes providing individuals who are homeless with safe and stable housing as quickly as possible, without placing any pre-determined expectations on the client, and then providing supportive services as needed. TOD has been nationally recognized as a successful and cost-effective program to improve HIV outcomes for its marginalized target population. We have published several studies demonstrating the effectiveness of this program, including the first and only study to date that uses viral load to measure the impact of the housing first model of care on homeless PLWHA (31, 32).

Though its initial mission was to provide supportive housing to marginalized PLWHA as a means of addressing homelessness, through mixed methods research conducted with residents of TOD we determined that clients responded positively to this service, credited it with their improved adherence, and in fact maintained TOD as their representative payee long after leaving the housing program. These facts suggest that this service can help prevent homelessness and

stabilize other health outcomes. In 2012, TOD expanded its CCRP services to make it available not only to individuals housed in its building but also to other PLWHA at risk for homelessness. In a recent satisfaction survey of 29 participants, 77% of CCRP clients who were housed at TOD and 92% of clients not housed at TOD reported being “satisfied” or “very satisfied” with CCRP services (33). Moreover, 90% of CCRP clients have kept the program as their Rep Payee for 12 or more months, and some clients as long as nine years, dating back to the time when TOD first began providing the service, further demonstrating acceptability of this intervention. Of people who have dropped from the intervention, 5 of them “graduated” from the program, meaning they had stabilized their housing and financial situations sufficiently to manage budgeting independently. One individual left the program after losing his SSI benefits due to incarceration, and only two left because they were unhappy with having someone else manage their money.

Two pilot studies suggest significant associations between CCRP and viral load. Our first study assessed changes in viral load data for 40 clients who received Client-Centered Rep Payee between December 2012 and January 2014. After excluding clients housed at TOD in order to remove any potential interaction with housing effects as well as clients that had no viral load data available at baseline, our final sample included 18 participants. Seven of the 18 participants (38.9%) had viral suppression at baseline (VL<200 copies/ml), and 16 (88.9%) of the 18 had achieved viral suppression at the six-month follow up ($p=.004$; McNemar’s test for paired data)(34). More recently we determined that of 40 participants receiving Client-Centered Rep Payee, 82% had suppressed viral loads at both 6- and 12-month follow ups. All of the clients who have received CCRP services to date were unstably housed, either chronically homeless or at risk for homelessness; demonstrated poor retention in care and/or had not achieved suppressed viral load; and had histories of serious mental illness and substance use. The results of these pilot studies are promising, but limited by small sample size and lack of control groups.

3.0 Approach

Achievement of our proposed aims and understanding the underlying mechanisms of this approach will help to shift the field of adherence research to emphasize client-centered, structural interventions. CCRP offers the possibility of improving housing stability and other outcomes that are correlated with adherence via a low-cost, highly replicable intervention that can be layered within clinical services. In addition, CCRP operates structurally in acknowledging the fact that adherence behaviors are unlikely to be altered without also addressing underlying challenges including those related to financial disadvantage. By stabilizing underlying mechanisms of adherence, clients are likely to experience multiple improved health outcomes, such as decreased stress and increased self-efficacy for health behaviors.

3.1 Innovation

This will be the first RCT to test the impact of financial management services on ART adherence and viral suppression. Given the well-documented associations between financial disadvantage and negative health outcomes, particularly HIV disparities, this approach is not only long overdue, but also may significantly change ways in which providers engage and retain clients in care. We are proposing multiple models of adherence measures, including those that are subjective (self-report via the CASE Adherence Index), objective (appointment adherence), and clinical (CD4 and viral load tests). Use of multiple measures of adherence improves the validity of findings of intervention effectiveness (18).

Including estimates of cost and cost-effectiveness adds critical information about the value of this intervention beyond clinical outcomes. In the United States in 2013, state and federal Medicaid spending on HIV care exceeded \$9.6 billion (35). Most people who receive Medicaid care qualify because they are disabled, have low income, and receive SSI, and therefore represent the target population for this intervention. Improving retention in care can significantly reduce the cost of HIV care in the US (36). CCRP may require a small investment yet result in significant cost savings to federal programs including Medicaid.

CCRP is a feasible approach that may change the clinical trajectory of HIV for the most marginalized PLWHA, whose health disparities are the drivers of this disease. This intervention has already been piloted with marginalized individuals including those who are homeless and unstably housed, as well as with individuals with criminal histories, mental health

diagnoses, active substance use disorders, and long histories of being dropped from care as a result of problematic behaviors. While many adherence interventions focus on stigma, knowledge, and access, CCRP addresses barriers to adherence that result from financial disadvantage. Patients who have initiated ART early in the spectrum of their disease may not have experienced the symptoms that are more common in late-stage HIV, which can be a source of adherence motivation. Because it does not build on cognitive models, CCRP can be provided to PLWHA across all stages of infection. A challenge inherent to understanding the long-term effectiveness of evidence-based ART adherence interventions is that they typically have a life span of two years or less (18). This is problematic because adherence is a life-long commitment, and because ART initiation is moving earlier into HIV disease stages.

CCRP requires a relatively low investment of resources, and can, therefore, be provided as long as clients receive Social Security entitlements. In addition, it is highly replicable. The intervention builds on a Social Security Administration policy that has been in effect for more than fifty years, which has often been used in clinical and community-based settings. If found to be efficacious as an adherence improvement mechanism, there is already a system in place through the Social Security Administration that would allow for rapid replication. In this sense, this study will test an approach to improving ART adherence that has been hiding in plain sight. By investigating the cost, cost-effectiveness, and underlying mechanisms that produce ART adherence and viral suppression, we can create a complete blueprint for how to implement a structural intervention for the most marginalized and resource-challenged PLWH. Using a mixed-methods approach will further help us define factors that improve client acceptance and retention and prepare the intervention for broad-scale replication. By the completion of this study, we will not only know the impact of CCRP on viral load and the costs of providing the intervention, but will also be able to streamline the intervention, creating a road map for rapid replication.

3.2 Hypotheses and Aims

We hypothesize that by helping clients to pay their rent and other bills on time, housing stability improves and financial stress decreases. By reducing the cognitive burden of living with chronic financial stress and frequent threats of housing loss, clients can devote more time and attention to medical appointments and medication adherence. Ultimately, we believe that this program improves clients' self-efficacy for health behaviors, retention in care, medication adherence, CD4 counts, and viral loads. We propose the following aims to test these hypotheses via a randomized controlled trial of 320 PLWHA .

Aim 1: Conduct a randomized controlled trial (RCT) to test the effect of Client-Centered Rep Payee on ART medication adherence and viral load among PLWHA who are economically disadvantaged and unstably housed.

We will compare clinical adherence through behavioral and biological measures including self-reported appointment adherence and viral load for clients receiving the intervention versus those receiving standard of care.

Aim 2. Test underlying mechanisms associated with Client-Centered Rep Payee that contribute to changes in medication adherence and viral suppression rates. We will use quantitative (mediation analysis) and qualitative (semi-structured interview) methods to test hypothesized mediators of medication adherence and viral suppression including financial and housing instability, financial stress, self-efficacy for health behaviors, and retention in care.

Aim 3. Assess the cost and cost-effectiveness of the Client-Centered Rep Payee model. We will conduct an economic analysis to model the impact of the intervention as compared with standard of care on quality-adjusted life years as well as new infections averted.

3.3 Study Design Rationale

The study team identified the RCT design as the most straightforward approach in terms of rigor, cost, and feasibility. Individuals who consent to participate will be randomized (1:1) to the standard of care control group or the standard of care plus CCRP intervention group. Though crossover and other study designs were considered, we were concerned about the degree to which contamination between study groups might occur given the nature of the interventions. That is, those who would be assigned the active intervention first and control second may learn and benefit from the active

intervention. To ensure one of the main benefits of the crossover design, which is that every participant receives the intervention, we have measures in place to provide CCRP to control arm participants once their study periods have concluded.

The study population is limited to PLWHA who are 18 years of age and older, English- or Spanish-speaking, recipients of Social Security entitlements (SSI and/or SSDI), not currently receiving representative payee services nor having received them in the past 12 months, income below 138% of the federal poverty level, and one or more of the following: not virally suppressed (>200copies/ml), unsustained viral suppression over the past 12 months, or poor ART adherence. As its standard of care, Action Wellness providers currently use either the CASE Adherence Index (poor adherence is indicated by a CASE Index score of ≤ 10) or by a single question to assess the percentage of missed dosages in the past week (poor adherence is indicated by a score of less than 90%). When using the CASE Index for screening eligibility the most recent CASE score must be used and the score cannot be more than 6 months old. These measures will be used to assess eligibility for this study, along with counts of unsuppressed viral load or unsustained viral suppression. New clinic clients who do not have historical viral load data but are not suppressed at baseline or who meet other inclusion criteria (poor self-reported adherence) will be eligible for the study.

These inclusion criteria will enable us to provide services to a population that historically struggles with ART adherence and low rates of viral suppression. We will also be able to assess the extent to which CCRP helps stabilize clients who may be virally suppressed at baseline but are not likely to stay that way due to poor adherence history. Including clients who have viral suppression at baseline but have poor adherence or have not sustained suppression over time is critical; a recent study that followed clients over a three year period found that of those who had viral suppression at baseline, 20-25% subsequently had viral failure or were lost to follow up (37).

4.0 Potential Risks and Benefits

4.1 Risks to Human Subjects

In order to test the impact of Client-Centered Rep Payee services on ART adherence of people living with HIV/AIDS (PLWH), we will randomize 320 individuals to intervention or control arms. Inclusion criteria are living with HIV/AIDS, 18 years of age and older, English- or Spanish-speaking, recipient of Social Security entitlements (SSI or SSDI), not currently receiving representative payee services nor having received them in the past 12 months, income below 138% of the federal poverty level, and one or more of the following: not virally suppressed, unsustained viral suppression over the past 12 months, or poor ART adherence. Poor adherence will be assessed via Action Wellness's current standard of care. Providers use either the CASE Adherence Index (poor adherence is indicated by a CASE Index score of ≤ 10) or by a single question to assess the percentage of missed dosages in the past week (poor adherence is indicated by a score of less than 90%). When using the CASE Index for screening eligibility the most recent CASE score must be used and the score cannot be more than 6 months old. New clinic clients who do not have historical viral load data but are not suppressed at baseline are eligible for the study if they meet other criteria. These inclusion criteria will enable us to provide services to a population that historically struggles with ART adherence and low rates of sustained viral suppression.

Action Wellness will serve as the intervention site for this study. Action Wellness is a community-based organization that provides comprehensive health services to PLWHA including clinical care, adherence support, supportive services, consumer education, research, and advocacy. Action Wellness provides clinical care to 2,100 PLWHA annually. Staff from Action Wellness will recruit and consent participants, implement the intervention, and provide data for analysis to the University of Pittsburgh. Study participants will be assigned a unique identifier. Action Wellness will provide de-identified participant data to the University of Pittsburgh team for analysis. All materials with identifying information, including consent forms, will be kept in double-locked filing cabinets at the study intervention site, or within a password-protected electronic database with no potential access by modem or other means.

4.1.1 Sources of Materials

Data collected from study participants will include that which is biological (CD4, viral load); behavioral, captured via self-report (collected electronically via use of tablets); and electronic data abstracted from Action Wellness's electronic health record (appointment adherence, exposure to services, and retention in care.) Self-report data will be collected at baseline, 3-month, 6-month, and 12-month time points. "Mini check-ins" will be conducted at months 1 and 9 of the study. Abstracted data will be collected at baseline, 6-month, 12-month, 18-month, and 24-month time points. Linkages will be made to human subjects using a unique participant ID; only staff at the Action Wellness will be able to link participant IDs with the data collected.

In addition, qualitative interviews will be collected with a subset of participants and with providers from Action Wellness. Semi-structured interviews with 40 study participants and 15 providers (physicians, nurse practitioners, medical social workers, Client-Centered Rep Payee (medical case manager and financial manager) will be conducted by the University of Pittsburgh team (PI, Project Coordinator, and doctoral student) to further contextualize findings from the mediation analysis. Interviews will take place in year 3 of the study, providing sufficient time to transcribe and analyze data and to provide a large enough pool of participants who have completed 12-month follow-up self-reported assessments. Members of the Action Wellness research team will inform study participants of the opportunity to participate in interviews to share feedback on the intervention, and link participants to the qualitative interviewers.

Finally, the study coordinating center will provide de-identified data from the study site to researchers from Johns Hopkins Bloomberg School of Public Health, who will conduct a cost-effectiveness analysis. These data include those collected via participant self-report (time spent by clients traveling to and from services, transportation costs to and from services, and HIV risk behavior) as well as those abstracted from the study site, (number of participants enrolled, number of client contacts, time spent by clients in service, wage level for clients, staff personnel costs, materials and consumables, and viral suppression.)

4.1.2 Potential Risks

The nature of some of the questions, particularly current sexual behaviors and/or current drug use behaviors, has the potential to distress some study subjects. The intervention site already has in place on-site supportive services and a clinical referral network for any participant who experiences emotional distress as a result of their assessment. An additional potential risk is that participants may experience feelings of coercion since their financial assets will be managed by a representative payee.

4.2 Adequacy of Protection against Risks

4.2.1 Patient Recruitment and Informed Consent

Participants will be recruited during regularly scheduled visits at the intervention site. Flyers announcing the opportunity to participate in the study will also be posted in the waiting and patient rooms. The research coordinators and medical case managers will screen clients for participation per the study inclusion criteria. The research coordinators or medical case managers will obtain written consent from eligible participants and provide them with information about study aims and approach, voluntary nature of participation, assessment and incentives schedule, and right to exit the study at will without penalty. Following recruitments, participants will complete a baseline survey. The research coordinator and medical case manager will follow up with participants at 3-, 6-, and 12-months to schedule completion of follow-up surveys. Mini check-ins will be conducted during months 1 and 9. Participants will be provided with gift cards in the amount of \$20 each time they complete the assessment tool and mini check-ins to honor their time, for a total of \$120. Assessments will be scheduled in conjunction with regular clinic visits to increase convenience for participants. Participants who take part in qualitative interviews will receive an additional \$40 in gift card incentives.

4.2.2 *Protections against Risk*

As noted above, the risks in this study are minimal and include possible feelings of distress due to answering questions about sexual risk and substance use behavior. To minimize this risk, participants will be informed of how data will be shared and with whom, and will be advised that they can withdraw from this study at any time.

An additional potential risk is that some participants may experience feelings of coercion given that their financial assets will be managed by a representative payee. This risk is minimized by emphasizing participant-driven decision-making, in which participants prioritize how funds are distributed, and by the fact that participants will be informed that they can withdraw from the study and payee service at any time. Payee services can be terminated by completing a form with the Social Security Administration; the medical case manager and research coordinator will keep these forms available and help participants in completing them at the behest of the participant.

Because Rep Payee is a policy currently in practice with the Social Security Administration, comprehensive policies and controls are already in place through the SSA and include issues specific to oversight, keeping finances secure, preventing identify theft, paper and electronic file securing, and protecting beneficiary bank accounts. Client-Centered Representative Payee (CCRP) as currently delivered by The Open Door, Inc. follows these each of best practices, which will be replicated at Action Wellness. SSA-sponsored safeguards include the following:

1. Adequate oversight is maintained and includes the requirement of a second staff member's approval required when a proposed disbursement exceeds a pre-set limit (\$2,000), countersignatures for checks that exceed this limit, monthly reconciliation of ledgers and bank records, internal audits, and outside audits.
2. Titling of accounts established for CCRP beneficiaries show that the representative payee has only a fiduciary (not personal) interest in the funds. This approach is used rather than establishing joint accounts, which means that the client cannot access the account without the organizational Rep Payee, and that the account is specifically used only for beneficiary purposes
3. Checks are kept in locked, access-controlled areas.
4. SSA policies and procedures to protect identity theft are maintained, and include shredding paperwork with identifying information and storing electronic files are stored in password protected files with no web access.
5. Beneficiary funds are protected in accordance with SSA policies, which include FDIC protection of up to \$250,000 per depositor in an FDIC insured bank. Since the intent of this intervention is that monies are managed on behalf of the beneficiary, clients do not know their account numbers and therefore cannot access funds without discussing with their organizational Rep Payee, or in this case, their case manager.
6. Funds are deposited by SSA directly into the beneficiary account, which minimizes the risk for mishandling of funds, check fraud, and lost checks. To further minimize these risks, bills are to be paid electronically when the biller has this option available, and expendable funds are distributed to the client via electronic check cards. These cards can be replaced if lost, and loaded remotely, further reducing risk of fraud or theft.
7. It is the policy of The Open Door that annually during the organizational audit, the outside auditor conducts an audit on a random sample of at least 30% of total Representative Payee accounts for misuse of funds prevention.
8. In addition, SSA reserves the right to randomly select organizational representative payees to ensure that appropriate safeguards are in place and that beneficiaries are being appropriately served under this policy. The Open Door was randomly selected for an audit in 2008 and received no negative findings.

9. Finally, Action Wellness will be bonded as an organizational representative payee to further protect study participants from harm or wrongdoing.

Any involvement in human subjects research carries some small risk of loss of confidentiality, which in this case would include loss of confidentiality of stigmatizing behaviors. This research is covered by a Certificate of Confidentiality from the National Institutes of Health. We will also ensure that participant ID numbers are used to identify study materials. In cases where participants are recruited and choose to participate in qualitative interviews with researchers from the University of Pittsburgh, members of the Action Wellness research team will provide information to the research team from the University of Pittsburgh about the participants' medical status, including viral load, CD4 counts, and medication and appointment adherence. Individuals who participate in qualitative interviews will be given a HIPAA notice to describe the use of protected health information and will be asked to sign a separate and specific consent form demonstrating their understanding of the use and limits of that information.

All materials with identifying information, including consent forms, will be kept in double-locked filing cabinets at the study intervention site, or within a password-protected electronic database with no potential access by modem or other means. (See Appendix A for Data Security Assessment form.) All study procedures will be reviewed by the institutional review boards of the University of Pittsburgh, Action Wellness, Johns Hopkins University, and the City of Philadelphia Department of Public Health.

4.3. Potential Benefits of the Proposed Research to Human Subjects

The potential benefits of the proposed research to study participants is that they may experience improved ART adherence and related outcomes as described in the research strategy if exposed to the Client-Centered Rep Payee intervention. The study has the potential benefit to PLWHA as a whole by offering an innovative approach to improving ART adherence, and in turn, reducing HIV health disparities.

4.3.1 Importance of the Knowledge to be Gained

Client-Centered Rep Payee is a feasible and highly replicable approach that may change the clinical trajectory of HIV for the most marginalized populations, whose health disparities are the drivers of this disease. Few adherence interventions that are structurally-based have been studied to date, so this approach may yield effects that are more durable than behavioral interventions. Client-Centered Rep Payee has already been piloted with marginalized individuals including those who are homeless and unstably housed, as well as with individuals with criminal histories, mental health diagnoses, active substance use disorders, and long histories of being dropped from care as a result of problematic behaviors, with no serious adverse effects noted. In addition, the representative payee practice is one that has been authorized and overseen by the Social Security Administration for many years; in this sense, it is a structural adherence improvement intervention that has been hiding in plain sight. For these reasons, possible study benefits far outweigh potential risks.

5.0 Subject Selection and Recruitment

5.1 Inclusion/Exclusion Criteria

5.1.1 CCRP Inclusion Criteria

- Living with HIV/AIDS
- 18 years of age and older
- English- or Spanish-speaking
- Recipient of Social Security entitlements (SSI and/or SSDI)
- Income below 138% of the federal poverty level
- One or more of the following:

- Not virally suppressed (viral suppression is denoted at 200 copies/ml)
 - Unsustained viral suppression over the past 12 months
 - Poor ART adherence. Poor ART adherence is assessed via a CASE Index Score ≤ 10 or via a single question to assess the percentages of missed doses in the past week $< 90\%$. (When using the CASE Index for screening eligibility the most recent CASE score must be used and the score cannot be more than 6 months old. New clients who do not have historical viral load data but are not suppressed at baseline will be eligible for the study if they meet other criteria.)
- Able and willing to provide informed consent

5.1.2 CCRP Exclusion Criteria

- Currently receiving Representative Payee services or having received them in the past 12 months.

5.2 Qualitative Interviews

5.2.1 CCRP Participants

Qualitative interviews will be conducted in year 3 of the study. All patient participants for the qualitative interviews will be recruited from the CCRP trial. Both intervention and control arm participants will be recruited. We will purposively sample clients for interviews based on their success or lack of success in improving ART adherence as well as improved biological measures. Members of the Action Wellness research team will link participants to the qualitative interviewers by coordinating interview appointments at the study site. Since we are interested in exploring factors related to adherence success, half of the interviews (in both arms) will be conducted with participants who have successfully achieved viral suppression while the other half (in both arms) will be conducted with participants who are not virally suppressed or who have poor medication adherence or retention in care. Our sampling approach will enable us to assess the degree to which the intervention contributed to adherence changes, as well as mechanisms underlying change.

5.2.2 Providers

The University of Pittsburgh investigators will reach out to Action Wellness providers to schedule in-depth qualitative interviews. Recruitment will occur via a regularly scheduled staff meeting in which investigators from the University of Pittsburgh will share an overview of the purpose of the interviews, confidential nature of data, and contact information of the investigators, which will be used to set up appointments for interview. Provider interviews will be voluntary and the investigators conducting the interviews will obtain verbal consent prior to obtaining and data or feedback from participating providers (Appendix B.) One-on-one interviews will be held in a private space at Action Wellness, will last 60-90 minutes, and will be audio recorded and professionally transcribed.

5.3 Subject Recruitment

Study enrollment targets are shown in Table 1. All interactions with participants and data collection will occur at the clinical site, Action Wellness. Participants will be recruited during regular visits at Action Wellness, including pharmacy and social services visits. Recruitment may take place during regularly scheduled appointments or during walk-in visits when clients interact with staff members. Flyers announcing the opportunity to participate in the study will also be posted in the waiting and patient rooms. To manage participant recruitment and enrollment, Action Wellness has developed a streamlined system using the Electronic Medical Record to flag clients who are eligible for studies. This system will be used for the CCRP study as well.

In addition, Action Wellness will host several educational workshops with its clients to share information about the study. These sessions will take place at the offices of Action Wellness and may begin before the active study enrollment period and continue periodically throughout the study as needed. Need for additional workshops will be determined by Action Wellness staff in response to client interest in the CCRP study. The workshops will be conducted by staff

members from The Open Door, Inc. and the focus will primarily be on how CCRP works. In addition, clients from The Open Door who have received CCRP will be invited to share their experiences, concerns, and perceived benefits related to CCRP services. *During these workshops, no activities related to consenting, enrolling, or randomizing participants in the study will be conducted.* Topics that will be addressed during these workshops include:

- Purpose of study
 - Improving ART adherence in the target population
 - History of TOD
 - Evaluation results from CCRP at TOD
- Discussion about CCRP and how it differs from traditional Representative Payee services.
- TOD client: personal perspective of CCRP
- Things to consider before deciding
 - Need for financial management (including difficulty with adherence, frequent eviction and/or shut-off notices, homelessness)
 - Readiness for financial management
 - How to get more information about the study
- Description of study methods
 - Voluntary nature of participation and right to withdraw
 - Potential risks and protections (de-identified data)
 - Randomization and right to receive free CCRP services through Action Wellness at the conclusion of the 12-month active study period (regardless of randomization arm)
 - Timeline (when recruitment will begin, survey schedule)
 - Incentives
- Question and Answer Period

Table 1. Enrollment Targets

	Year 1 6/2017 - 5/2018				Year 2 6/2018-5/2019				Year 3 6/2019-5/2020				Year 4 6/2020-5/2021				Year 5 6/2021-5/2022			
	Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4	Qtr1	Qtr2	Qtr3	Qtr4
Submitted 4/2018			3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	3/19-5/19	6/19-8/19	9/19-11/19	12/19-2/20	3/20-5/20	6/20-8/20	9/20-11/20	12/20-2/21	3/21-5/21	6/21-8/21	9/21-11/21	12/21-2/22	3/22-5/22	
<i>Enrollment N by Quarter</i>																				
Enrollment/Baseline Assessment			15	15	25	25	30	30	30	30	30	30	30	30						
3-Mo Assessment				15	15	25	25	30	30	30	30	30	30	30	30					
6-Mo Assessment					15	15	25	25	30	30	30	30	30	30	30	30				
12-Mo Assessment							15	15	25	25	30	30	30	30	30	30	30	30		

Recruitment and participant inclusion/exclusion criteria are described in sections 3.1 and 3.2 above.

5.3.1 Screening

Action Wellness Research Coordinators and medical case managers will use the EMR system to screen clients for participation.

5.3.2 Consent

Signed informed consent will be obtained by the Research Coordinators or medical case managers at Action Wellness.

The consent form (Appendix B) includes all of the study procedures, information about potential risks and benefits of participation, and information regarding who participants can contact for further questions. Before any other study procedures take place, each participant will read and review the Informed consent with study staff and allowed time to ask any questions they have before signing the form.

5.3.3 Retention

The Action Wellness research coordinators will track participant retention, which will be reviewed bi-weekly by the PI (Hawk) and co-PI (Hagan.) Though loss to follow-up is a concern, this is lessened by the use of incentives for follow-up assessments in both study arms as well as by the fact that participants receive clinical and supportive services at the study site and are therefore more likely to remain in the study. If needed, medical case managers at Action Wellness will meet with participants to address concerns and prevent drop-out.

5.4 Incentives

Participants in both arms will receive a \$20 gift card from Action Wellness each time they complete the client assessment tool, *i.e.*, at Baseline, 3-months, 6-months, and 12-months, and mini- check-ins at 1- and 9-months. In addition, 40 participants (20 in the intervention arm and 20 in the control arm) will be recruited to qualitative interviews. Participants who complete interviews will receive another \$40 in gift card incentives.

5.5 Study Participation

5.5.1 Study Withdrawal

Participants may withdraw from this research study, which means they will also be withdrawn from further participation in this research study. Any study data or medical information obtained as part of this study prior to the date of consent withdrawal will continue to be used and disclosed by the investigators for the purposes described above. To formally withdraw from this research study, participants will be asked to provide a written and dated notice of this decision to the Principal Investigator of this research study at the address listed on the consent form. Participants who are unable to provide written consent will provide verbal consent to the Action Wellness research coordinator, who will document their desire to withdraw. Participants' decisions to withdraw from this study will have no effect on their current or future relationships with the University of Pittsburgh. Also, the decision to withdraw consent for participation in this research study will have no effect on their current or future medical care at Action Wellness.

5.5.2 Study Termination

Participants may be withdrawn from the study if they are also withdrawn from Action Wellness patient services. In keeping with Action Wellness policy, clients may be terminated from care if they pose an active threat to others; *i.e.*, violently act out or place credible threats against other clients or providers. In the event that participants are withdrawn, the study team will provide active referrals to other local providers to ensure continuity of care and that Rep Payee services are continued (if the participant was assigned to the intervention arm).

5.5.3 Voluntary Nature of Participation

Participation in this research study is entirely voluntary. Participants are encouraged to discuss this study with family, friends, and other trusted resources before agreeing to participate. Before obtaining consent, participants will be encouraged to ask for clarification of any points they do not understand. Study investigators will be available to answer current and future questions. Whether or not individuals elect to provide consent for participation in this research study will have no effect on their current or future relationship with the University of Pittsburgh, or on their current or future medical care at Action Wellness or current or future relationships with a health care insurance provider. The site investigator is interested in both patient care and in the conduct of this research study. Before agreeing to participate in this research study, or at any time during study participation, participants may discuss their care with another doctor

who is not associated with this research study. Clients of Action Wellness are not under any obligation to participate in any research study offered by their doctors.

5.5.4 Assignment of Rep Payee

This study seeks to improve health outcomes for people who meet study inclusion criteria and who struggle with bill payment and medication adherence. Action Wellness will work with participants who are randomized to the intervention group to enroll them in Rep Payee services. Rep Payee assignment occurs not at the convenience of the client, but only when SSA determines that there is a need for assignment. To demonstrate need, individuals who elect to participate in the study and are randomized to the intervention arm will be asked to complete a form with their case manager indicating their need and requesting that SSA appoints Action Wellness as their Organizational Rep Payee (SSA-787 “Physician’s/Medical Officer’s Statement of Patient’s Capability To Manage Benefits”). The participants’ physician will also be asked to sign off on this form, indicating that they agree that Rep Payee would benefit the client. At that point, SSA will decide whether or not Action Wellness can be assigned as Rep Payee. If for some reason the doctor or SSA does not agree that the participants would benefit from Rep Payee services, participants can still stay in this study but will not receive Rep Payee services from Action Wellness.

Participants who are randomized to the control group but who feel they have the need for representative payee services may also elect to receive Rep Payee services at the end of their 12-month active study period. These participants will be asked to complete a form indicating need and requesting that SSA appoints Action Wellness as their Organizational Rep Payee (SSA-787 “Physician’s/Medical Officer’s Statement of Patient’s Capability to Manage Benefits”). The participants’ physician will also be asked to sign off on this form, indicating that they agree Rep Payee would benefit the client. At that point, SSA will decide whether or not Action Wellness can be assigned as Rep Payee.

5.5.5 Withdrawal from Rep Payee

Participants can ask to have Action Wellness removed as their Rep Payee at any time in the study. If participants no longer want Action Wellness to act as their Rep Payee and feel they are able to pay their bills independently, Action Wellness will help participants to have SSA remove Action Wellness as the Rep Payee. This will include asking the participants’ physician to sign off on the paperwork indicating that Rep Payee is no longer needed (SSA-787 “Physician’s/Medical Officer’s Statement of Patient’s Capability to Manage Benefits”). If the physician feels the participant still needs help from a Rep Payee and the participant disagrees, their case manager at Action Wellness will work with the participant to understand why they feel they are ready to pay their bills independently. If the participant is able to demonstrate financial independence, the case manager will accompany the participant to SSA to provide a signed “third party” statement explaining that they have direct knowledge of the participant’s ability to pay bills independently. If SSA does not agree to have Action Wellness removed as organizational Rep Payee, Action Wellness will help the participant appeal this decision. This will include linking the participant to free legal services if needed. Action Wellness can also help the participant identify a different Rep Payee if desired by the participant.

6.0 Study Procedures

6.1 Randomization

Patients who elect to participate will be assigned to the intervention or control with a 1:1 allocation ratio via a simple randomization procedure. A permuted block design was rejected in order to avoid the predictability of the intervention assignment given that the intervention is unmasked. We will monitor the randomization process throughout the study period to ensure there are no systematic differences between study arms and no selection or assignment biases. REDcap forms will be used to return randomization. When a member of the Action Wellness research team receives consent to participate from an individual, a unique identifier will be generated via REDcaps, which will return the assignment to the study arm.

Participants randomized to the control arm will continue to attend medical visits in keeping with the Action Wellness’ standard of care and normal operating procedures. Participants randomized to the intervention will receive the same care in addition to CCRP. We will assess for exposure to representative payee services throughout the study period to ensure that if control group participants elect this service through family members or other providers we are able to control for this in our mediation analysis. At the conclusion of the study, clients randomized to the control group will be offered CCRP services, ensuring that all clients have the opportunity to benefit from the intervention.

6.2 Data Collection

Participants in both arms will complete the assessment tool at baseline, 3-, 6-, and 12-month time points. Mini-check-ins will also be conducted in months 1 and 9. Viral load, CD4, and appointment adherence data will be monitored at baseline, 6- and 12-months, as well as 6- and 12-months after the participant’s active study period. Since many individuals who receive ART often achieve viral suppression within 3-6 months, these time points will provide appropriate opportunities to detect shifts to viral suppression as well as persistence of viral suppression over time. Assessment variables are described in Table 2 and the full assessment tool is attached as Appendix C. During the baseline visit, intervention arm participants will also complete the SSA Request for Representative Payee. Section 7.0 provides additional detail regarding this process.

Clinical data will also be abstracted from participant electronic medical records at Action Wellness as shown in Table 2. Additional detail regarding data abstraction and management are included in section 11.0.

Table 2. Key Study Variables with Measurement Tools and Data Collection Points

Construct	Scale	Items	Data Collection Points
ART Adherence			
HIV Biomarkers	Action Wellness Data Abstraction	CD4, Viral Load; continuous variables	Baseline 6-months 12-months 18-months 24-months
Sociodemographics	Self-report: HRSA reporting measures	Age, race, gender, date of first diagnosis (if known), income, HIV transmission risk behavior	Baseline
ART Adherence	Self-report: CASE Adherence Index	3 items 1. How often do you feel that you have difficulty taking your HIV medications on time? 2. On average, how many days PER WEEK would you say that you missed at least one dose of your HIV medications? 3. When was the last time you missed at least one dose of you HIV medications?	Baseline 3-months 6-months 12-months
Housing Instability			
Housing Status 1	Self-report: Wolitski, et. al., 2010	One item: “Which best describes your current living situation?” (Stably Housed/Unstably House/Homeless)	Baseline 6-months 12-months
Housing Status 2	Self-report: Newly developed by team	“In the past 90 days, have you (a) Received an eviction notice or notice to vacate because your rent was not paid? (b) Had your utilities shutoff because your bill was not paid?”	Baseline 6-months 12-months
Self-Efficacy for Health Behaviors			
Self-efficacy for adherence	Self-report: HIV-ASES, Johnson, 2007	12-item scale designed to assess self-efficacy for taking HIV medications.	Baseline 6-months

			12-months
Financial Stress			
Self-report of financial stress	Self-report: Financial measures from Background Stress Inventory	5 item scale: In the past month, how often did you feel distressed by the following? 1. Finding the time to pay your bills by the due date. 2. Not being able to pay your bills. 3. Unexpected events requiring additional spending that exceed your budget (e.g. vehicle repair and urgent medical attention.) 4. Existing and/or growing debt. 5. Consequences of late payments (such as having utilities shut off.)	Baseline 3-months 6-months 12-months
Retention in Care			
Retention in Care	Action Wellness Data Abstraction (HRSA HIV/AIDS Bureau Reporting Measure)	<ul style="list-style-type: none"> • Proportion of missed versus total scheduled visits • Verification of at least one primary care visit per quarter • 2 kept visits separated by ≥ 90 days (dichotomous, 'yes' =retained) 	Baseline 6-months 12-months
Additional Variables			
Health/Mental Health Quality of Life	Single Item General Health Measure (SF-12; DiSalvo, 2006)	In general, would you say your health is: (Excellent, Very good, Good, Fair, Poor)	Baseline 6-months 12-months
Experiences of Payeeship	Self-Report: Rosen et. al., 2005	17-item questionnaire with 4 subscales: <ul style="list-style-type: none"> • Satisfaction with payee/case manager • Involvement of beneficiary in money management • Perceived benefit from payee arrangement • Feeling coerced 	6-months (intervention arm) 12-months (intervention arm)
Substance use	Risk Assessment Battery	40-item scale assessing substance use and sexual risks.	Baseline 6-months 12-months
Depressive Symptoms	Quick Inventory of Depressive Symptomology	16-item scale; self-report of depressive symptoms	Baseline 6-months 12-months
Connections with providers	Health Care Relationship Trust Scale	15-item scale assessing patient provider relationship; i.e., discussion options, committed to best care, interested in me as a person, excellent listener, accepts me, tells me complete truth, trusts me as an individual, makes me feel I am worthy of his/her time, takes time to listen, comfort talking about personal issues, feel better after seeing healthcare provider.	Baseline 6-months 12-months
Exposure to Services	Action Wellness Data Abstraction	Number of supportive services provided by Action Wellness during study period (where/how often): <ul style="list-style-type: none"> • Adherence support • Housing support – financial assistance • Housing support – place to stay Transportation support • Medical case management • Peer navigation • Meetings with Medical Case Manager to discuss 	Baseline 6-months 12-months

		Representative Payee	
Social Support	MOS-SSS	Five items from MOS-SSS that assess emotional, informational and tangible functional forms of social support.	Baseline 6-months 12-months
Additional Variables for Economic Analysis			
Wage level for clients	Abstraction	US Department of Labor website	Baseline 6-months 12-months
Time spent traveling to meet with MCM regarding CCRP	Newly developed by team	How long does it take you to travel one- way to visit with your Medical Case Manager?	Baseline 6-months 12-months
Transportation cost for clients	Self-report	How much does it cost you to travel one-way to visit with your Medical Case Manager?	Baseline 6-months 12-months
Staff personnel costs	Action Wellness Data Abstraction	Accounting records and budgets	One-time – not participant specific
Materials and consumables	Action Wellness Data Abstraction	Accounting records and budgets	One-time – not participant specific

6.2.1 Cost, Cost Threshold, and Cost-Utility Analyses

The University of Pittsburgh will manage the transfer of de-identified data from the study site to researchers from Johns Hopkins Bloomberg School of Public Health, who will conduct a cost-effectiveness analysis. The cost-effectiveness analysis will use de-identified data from the study site including those collected via participant self-report (time spent by clients traveling to and from services, transportation costs to and from services, and HIV risk behavior) as well as those abstracted from the study site (number of participants enrolled, number of client contacts, time spent by clients in service, wage level for clients, staff personnel costs, materials and consumables, and viral suppression.)

7.0 CCRP

CCRP will be embedded within existing services at the clinical site (Action Wellness.) During the baseline visit, intervention arm participants will also complete the SSA Request for Representative Payee. SSA authorization typically occurs within 3 months. Clients may terminate the representative payee appointment as described in section 5.5.5. The case manager will assist clients who are unable to complete the form independently due to literacy issues.

The case manager will help the client to create a budget and prioritize expenditures, focusing on housing and utilities in order to enhance housing stability. The medical case manager therefore will become the point-person for the CCRP service. Money management will be provided by the CCRP financial manager who will set up a bank account on behalf of the client; case managers do not have access to the participants’ accounts nor will be responsible for payment of bills.

Once the SSA authorizes the organizational payee, Social Security entitlements (SSI and/or SSDI) will be sent directly to that account. Checks or electronic transfers will be paid by the financial manager directly to the billers including landlords and utility companies. The financial manager will not be identified to the client, which not only is a safety precaution but will also help to ensure that discussions about budgeting and practical needs become part of the ongoing conversation between the client and the case manager.

Rep Payee responsibilities include the following:

- Case managers will meet with participants on a regular basis to understand their needs and help them develop monthly budgets. Participants will work with their case managers to decide how they want their bills to be paid, how they want extra money to be distributed, and if they want to develop a savings plan.

- Decisions about bill payment occur between the case manager and the client. The financial manager, who is responsible for bill payment, will follow the plan set forth by the client in collaboration with the case manager. The financial manager will not make spending decisions that vary from this pre-determined budget.
- Action Wellness will ensure that participants' funds are being used in the participants' best interest.
- Action Wellness will keep detailed records of how bills are paid in order to provide an accurate report to SSA when they ask for that.
- Action Wellness will complete all accounting forms as required by SSA.
- Action Wellness will report events that may affect participants' benefits, including death or incarceration.
- Action Wellness will follow all other rules as set by SSA. Printed copies of SSA requirements will be made available to participants throughout the study.

Throughout the course of the study, the research team will follow safeguards including those specified by the SSA to ensure the protection of clients. These safeguards are specific to oversight, keeping finances secure, preventing identify theft, paper and electronic file securing, and protecting beneficiary bank accounts and are detailed in section 4.2.2.

8.0 Data and Safety Monitoring Plan

8.1. Summary of the Protocol

The overarching goal of the study is to examine the impact of Client Centered Representative Payee services (CCRP) on antiretroviral treatment adherence outcomes for marginalized PLWHA. This will be tested via the following aims:

- (1) Conduct a randomized controlled trial (RCT) to test the effect of CCRP on anti-retroviral (ART) medication adherence and viral load among PLWHA who are economically disadvantaged and unstably housed. We will compare clinical adherence through behavioral and biological measures including self-reported appointment adherence and viral load for patients receiving the intervention versus those receiving standard of care.
- (2) Test underlying mechanisms associated with CCRP that contribute to changes in medication adherence and viral suppression rates. We will use quantitative (mediation analysis) and qualitative (semi-structured interview) methods to test hypothesized mediators of medication adherence and viral suppression including financial and housing instability, financial stress, self-efficacy for health behaviors, and retention in care.
- (3) Assess the cost and cost-effectiveness of the CCRP model. We will conduct an economic analysis to model the impact of the intervention as compared with standard of care on quality adjusted life years as well as new infections averted.

Participants (n=320) will be randomized to the intervention or to the standard of care. The study period is May 2017 – April 2022. Participant duration in the study is 12 months, with viral load and CD4 data monitored for an additional 12 months. Inclusion criteria to be screened at the study include (a) living with HIV/AIDS, (b) 18 years of age and older, (c) English- or Spanish-speaking, (d) recipient of Social Security entitlements (SSI or SSDI), (e) not currently receiving representative payee (“Rep Payee”) services nor having received them in the past 12 months, (f) income below 138% of the federal poverty level, and (g) one or more of the following: not virally suppressed, unsustained viral suppression over the past 12 months, or poor ART adherence.

Viral load, CD4, and appointment adherence data will be collected at baseline, 6 months, 12 months, 18 months, and 24 months via abstraction from Action Wellness patient records. Staff at Action Wellness will recruit, screen, and consent participants, and a full-time Rep Payee employed by Action Wellness will provide financial management to participants.

Action Wellness staff members will also maintain responsibility for data collection via client records data abstraction and by following up with participants to collect self-report data on electronic tablets. All participant interaction will take place at Action Wellness in Philadelphia, PA. Some participants will also be asked if they are willing to be interviewed by a researcher from the University of Pittsburgh to explore their responses to Rep Payee and its effect on medication adherence. In addition, 15 individuals who provide intervention services to study participants will be recruited to participate in qualitative interviews to explore their responses to CCRP and its effect on medication adherence. Lastly, 15 individuals who provide intervention services to study participants will be recruited to participate in qualitative interviews to explore factors perceived to contribute to ART adherence, specifically examining the effects of our hypothesized mediators.

8.2 Roles and Responsibilities

The PI (Hawk) will appoint an external Data and Safety Monitoring Board (DSMB), which will minimally consist of a biostatistician, an HIV physician engaged in research, and a community advocate with a strong understanding of health-related research. This committee will monitor the study, advise the NIH Program Office, and provide input to Dr. Hawk, Dr. Brooks, and the research team. The DSMB will approve the study protocol before patient recruitment is initiated. The Epidemiology Data Center (EDC) statisticians will provide a summary report to the PI on a weekly basis to enable monitoring of study recruitment and will establish a monitoring plan for study outcomes. The PI will in turn report to the DSMB, which will monitor accruing data, protocol deviations, and Serious Adverse Events (SAEs). The PI will convene the board at least once a year to confirm that the clients in the trial are being cared for safely.

The PI and the EDC will train the study site to ensure that most updated version of the study protocol is utilized and to orient staff members to the Data and Safety Monitoring Plan, including reporting responsibilities. We have created a system in which the study site will use an Event/Problem form to report events to the PI, who will then review to determine if the criteria have been met for Adverse Event, Serious Adverse Event, or Unanticipated Problem.

8.3 Trial Safety

Adverse events will be monitored via expedited reporting of SAEs that are unexpected and related to the study protocol to the DSMB members and study team, the scheduled reporting of adverse events and study outcome event rates to DSMB members on a semiannual basis, and the monitoring of the study outcomes by assigned intervention group on an annual basis. The DSMB may advise early termination of the trial for safety reasons or make other recommendations regarding modifications to the protocol.

This study has limited risks for participants. The nature of some of the questions, particularly current sexual behaviors and/or current substance use behaviors, has the potential to distress some study subjects. The study site (Action Wellness) already has in place on-site supportive services and a clinical referral network for any participant who experiences emotional distress as a result of their assessment. This risk is low because all data are reported confidentially or anonymously, because participants will submit self-report data on a computerized tablet, and because participants can choose to drop out of the study at any time.

An additional potential risk is that some participants may experience feelings of coercion because their money will be managed by a Rep Payee. This risk is minimized because participants will decide with their case managers how funds will be distributed. In addition, participants can withdraw from the study and/or from Rep Payee service at any time. If participant elects to terminate Rep Payee services, Action Wellness will help participants complete the necessary paperwork to do so. This paperwork may include asking the physician to sign off on a form indicating that Rep Payee is no longer needed (Physician's/Medical Officer's Statement of Patient's Capability to Manage Benefits). If the physician declines to sign off, study staff at Action Wellness will provide a signed "third party" statement explaining that participants are able to self-manage their benefits. SSA has no formal policy preventing the removal of individuals from Rep Payee. In the unlikely event that SSA does not agree to have Action Wellness removed as the Rep Payee, Action Wellness will help the participant to appeal this decision or to appoint a different Rep Payee if preferred by the participant.

Any involvement in human subjects research carries some small risk of loss of confidentiality, which in this case would include loss of confidentiality of stigmatizing behaviors. To minimize loss of confidentiality, we are using anonymous participant ID numbers to identify study data. Only those people who participate in qualitative interviews will have their names and contact information shared with researchers from the University of Pittsburgh so that interviews can be arranged. These will be removed from all records at the University of Pittsburgh once the interview is complete. All materials with identifying information, including consent forms, will be kept in double-locked filing cabinets at the study intervention site, or within a password-protected electronic database with no potential access by modem or other means.

8.4 Adverse Events, Serious Adverse Events, and Unanticipated Problems

Adverse Events: By definition, an adverse event is an untoward or unfavorable medical occurrence in a human participant, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with a person's participation in the research, whether or not considered related to a person's participation in the research.

Serious Adverse Event (SAE): The US Department of Health and Human Services Office for Human Research Protections (OHRP) defines SAEs as any adverse event temporally associated with the subject's participation in research that meets any of the following criteria:

1. Results in death;
2. Is life-threatening (places the subject at immediate risk of death from the event as it occurred);
3. Requires inpatient hospitalization or prolongation of existing hospitalization;
4. Results in a persistent or significant disability/incapacity;
5. Results in a congenital anomaly/birth defect; or
6. Any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of substance dependency or substance use disorder). (Modified from the definition of serious adverse drug experience in FDA regulations at 21 CFR 312.32(a).)

Unanticipated Problems: OHRP considers unanticipated problems, in general, to include any incident, experience, or outcome that meets *all* of the following criteria:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
2. Related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and,
3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

This trial is designed to test the effect of CCRP on viral load and other clinical markers among persons with HIV. The risks in this study are minimal, and we do not expect any adverse events to occur as a consequence of participation in this research study. This study, however, involves a high-risk patient population, and the natural progression of HIV/AIDS does include a large number of expected adverse events unrelated to participating in this research study. Given these circumstances, the trial investigators propose to limit the tracking and submission of adverse events to those that are:

1. Related to the attendance of a study visit, or,

2. Related to the study intervention.

Below is a description of the expected adverse events and other expected incidents, experiences and outcomes that are related to this trial.

Expected Adverse Events: None. The risks in this study are minimal and adverse events related to participating in this research study are not expected to occur.

Expected Incidents, Experiences or Outcomes: Based on prior experience with the Social Security Administration and Rep Payee services, the following issues may occur. These do not meet the definition of an adverse event (i.e., are not untoward or unfavorable medical occurrences). If such issues occur during this study, they will be evaluated to determine if they meet the criteria for unanticipated problems.

- Social Security Administration fails to deposit participant's Social Security entitlements.
- Social Security Administration deposits a lower-than-expected amount of Social Security entitlements.
- Checks or electronic transfers for rent/utilities/other expenses are delayed or not received.
- Expendable funds are delayed or not transferred to the participant.

8.5 Reporting Policy and Timeframe

In keeping with NIMH Policy, the written notice of reportable events will be provided to the NIMH Program Official in keeping with the following timeframes.

- IRB/DSMB suspension or termination – within 3 business days of receipt (Regulatory entity and PI)
- Deaths related to study participation – within 5 business days of the PI first learning of the death (PI)
- Unexpected SAEs related to study participation – within 10 business days of the study team becoming aware of the SAE (PI)
- Unanticipated problems involving risks to participants or others – within 10 business day of the PI learning of the event (PI)
- Serious or continuing noncompliance – within 10 business days of IRB determination (Institution)
- Adverse event – summary provided in annual progress report (PI)
- Protocol violations – annual progress report (PI)

8.6 Data Management

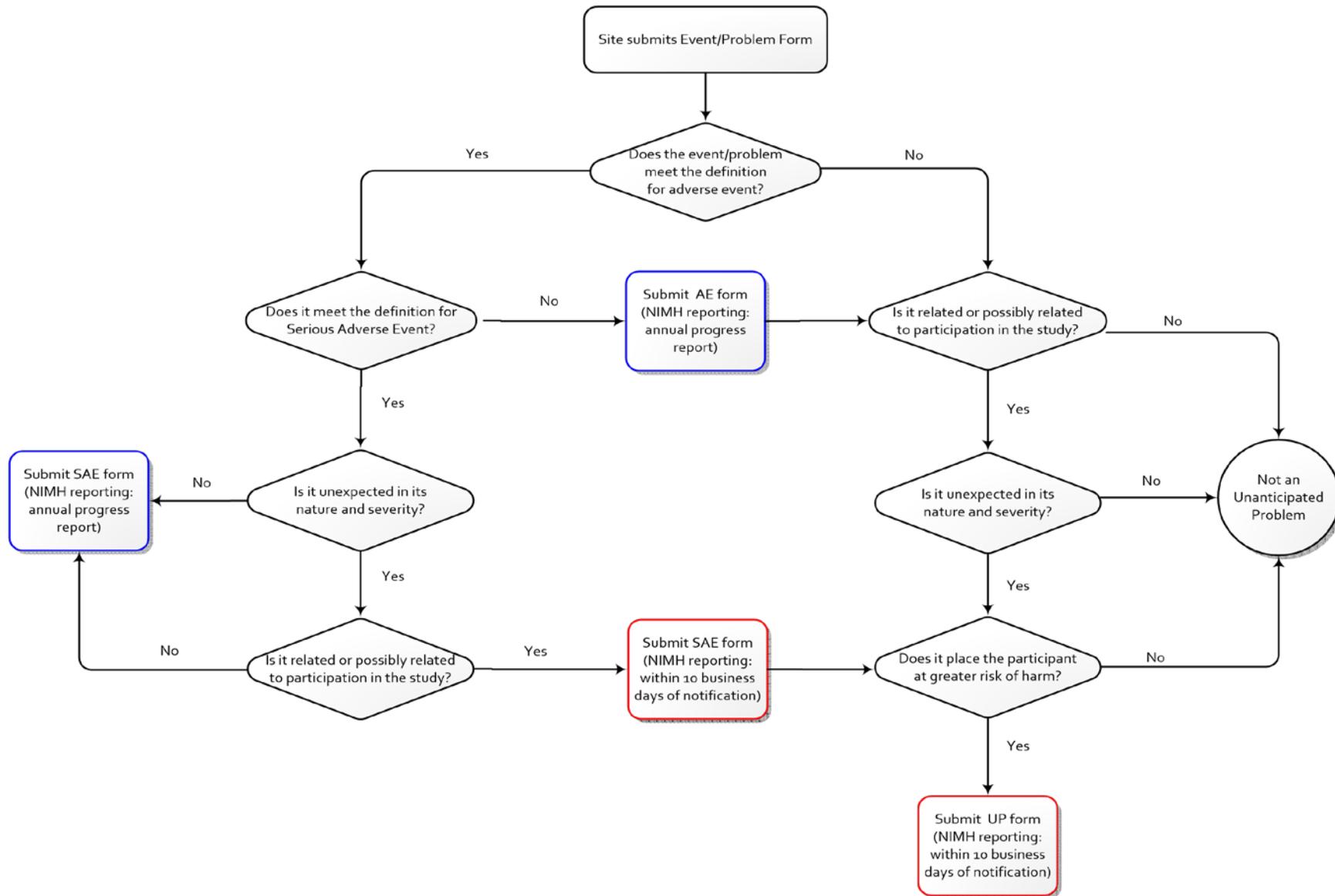
Data that is abstracted from patient records at the study site will be collected by the study site and provided to the Coordinating Center via a scheduled transfer using PittBox as a temporary transfer vehicle. Data will be deleted from Pittbox within 24 hours of scheduled transfer then uploaded to a Pitt department managed server. Client self-report data and tracking forms (off protocol, events) collected through computerized tablets will be stored on Pitt department managed servers. To minimize loss of confidentiality, we will ensure that participant ID numbers are used to identify study materials. All materials with identifying information, including consent forms, will be maintained separately from the study materials and will be secured per the study site's security policy and approved per the local IRB. Additional information regarding protection against risk is discussed in section 4.2 of the study protocol.

Qualitative data will be collected by researchers from the Coordinating Center. An Olympus DS3500 portable recorder with 256bit file encryption and device PIN locking will be used to record the semi-structured interviews (n=40 participants and 15 providers). The audio recording will be transferred to a Pitt desktop, transcribed, and imported into qualitative analysis software. The Pitt desktop utilizes encryption software. The audio recording will be permanently erased from the portable recorder. The study site will link abstracted and self-report data to participants recruited to the qualitative interviews so that that these data can inform the interview questions.

The data analysis plan for this study is described in section 9.0 of this protocol.

A plan for quality assurance and control is described in section 10.0.

Figure 3. Adverse Events Flowchart



9.0 Statistical and Analytical Plan

9.1 Approach

We will use mixed methods to explore underlying mechanisms contributing to changes in adherence and viral suppression rates (Aim 2). These methods include a mediation analysis, process measures, survey measures, and qualitative interviews. The mediation analysis will test the causal chain in which we hypothesize that adherence is improved, as shown in Figure 2. It will also enable us to explain any variance in study outcomes. If adherence is not improved for all intervention participants we will be able to detect why and what additional supports may be needed. Process measures include number of contacts with providers, which will be extracted from the Action Wellness electronic health records. The number of months in which CCRP was provided will be reported by the CCRP financial manager.

Statistical analyses will be conducted by the NIH-funded Epidemiological Data Center at the University of Pittsburgh Graduate School of Public Health. For each of the specific aims and hypotheses of interest, an initial descriptive analysis of all available data will involve summary statistics and exploratory data analysis (EDA) techniques. These strategies will be used to: 1) describe the individual and combined distributions of observed variables of interest; 2) ascertain the correlation structure among the variables; and 3) examine the necessary assumptions for subsequent statistical techniques. If the assumptions for any proposed statistical test are not met, the data will be transformed or a nonparametric alternative will be used.

Despite our efforts to minimize dropouts and other sources of missing data, we expect to encounter this problem. The intention-to-treat principle will be used for all primary analyses designed to compare outcomes between the assigned intervention groups. Missing data patterns will be examined prior to analyses. Our strategies will include utilizing data collected after participant dropout when possible, adjustment for covariates related to missing data in maximum likelihood models, the application of multiple imputation algorithms, adjustment for an independent variable reflecting actual time in the intervention, and the use of pattern mixture models incorporating completion status of each patient.

9.2 Objectives and Primary Comparisons

Primary outcome variables (Aim 1) include HIV medication adherence measured via viral load, appointment adherence/retention in care, and self-report using the CASE adherence index. Patients' CD4 and viral load counts are currently tracked as standard of care for Action Wellness on a quarterly basis, and these values will be provided to the University of Pittsburgh via data extraction from electronic health records. Appointment adherence/retention in care will be calculated via three previously validated and common ways: (a) the proportion of missed or rescheduled visits versus total scheduled visits every six months, (b) verification of at least one primary care visit per quarter, and; (c) two appointments in the past 12 months occurring at least 90 days apart (Health Resources and Services Administration) All data sharing will be fully Health Insurance Portability and Accountability Act (HIPAA) compliant. Additional detail regarding study variables is provided in Table 2.

Some primary outcome variables will be measured via survey data, as described in Table 2 and Appendix C. Combining biological, electronic, and self-report data on adherence provides the opportunity to triangulate results and obtain a more complete picture of ART adherence for study participants. Survey data will be collected at baseline, 3-, 6- and 12-month time points.

The primary comparisons of the randomized intervention groups for the viral load outcome will be conducted with an alpha level of 0.05; an alpha-level of 0.01 will be used for the other primary outcome variables in order to adjust for multiple comparisons. For each continuous outcome measure, a linear mixed effects model will be constructed with the

follow-up outcome measures as dependent variables, with the assigned intervention group, follow-up time, and corresponding baseline measure as independent variables, and with a random intercept term to account for within-subject correlation. All clients with at least one outcome value will be included in the models since linear mixed models account appropriately for data missing at random (MAR). We will compare both baseline characteristics as well as intermediate outcome values between clients with missing outcome data and those with complete outcome data. We anticipate that some patient factors will be significantly associated with missing data, and thus, that the data will not be missing completely at random (MCAR). It is difficult to distinguish whether outcome data are missing at random (i.e., missing at random conditional on known and observed factors, MAR), or the data are missing not at random (MNAR). We will take precautions to adjust for the observed factors associated with the missing data patterns in the primary analyses and will use models that appropriately account for data missing at random. If concerns about missing data remain, pattern mixture models will be used to account for the various observed missing data patterns.

Non-linear mixed models using a binomial link will be used for binary outcome measures. The significance of the coefficient of the intervention term is the primary test of the intervention main effect. Adjustment for the baseline level of the measure effectively means that we are comparing the “changes” from baseline. An interaction (i.e., the product term) between follow-up time and intervention group will be added to test whether the effect of the intervention differs over the follow-up course. Mixed models accounting for confounding factors and moderating factors will be conducted as secondary analyses based on the initial exploratory data analyses.

9.2.1 Sample Size and Power Calculations

In HIV-infected clients, ART has been shown to have a dramatic effect on viral load and CD4 cell counts (53). Since the control group will also have access to treatment, we conservatively estimate that the observed between-group standardized effect size in this trial will be between 0.33 and 0.50 [i.e. Platten, et. al. showed that treatment with ART increased CD4 cell counts from 210 / μ L to 410 / μ L, a 95% increase, and viral load was reduced (to under 50 copies /mL) in 91% of clients.] Based on the data presented in that paper, an effect size between 0.33 and 0.50 is reasonable for ART therapy in a broad population. Moreover, an effect size of 0.33 to 0.5 is generally considered small to medium (61), and we designed our trial to have power to detect modest effects for this intervention. Using a two-sided inequality hypothesis test and a two-sample t-test with $\alpha=0.05$, we determined the samples sizes required to provide 80% and 90% power to detect varying effect size differences between the two assigned treatment groups (Table 3).

Table 3. Sample Size Required to Detect Specified Effects

Effect Size	Sample Size for 80% Power	Sample Size for 90% Power
0.30	352	470
0.35	260	346
0.40	200	266

Based on these estimates, we plan to enroll a sample of 320 participants. If greater than 90% of participants contribute at least some follow-up data, the trial would have 288 clients with analyzable outcome data. This study would then have 80% power to detect a difference between the intervention and control groups of 0.331 SDs, and 90% power to detect a difference of 0.383 SDs. For other outcomes where analyses are based on an $\alpha=0.01$, the study would have 80% power to detect an effect size of 0.405. Since 0.20 to 0.30 is considered a small effect size and 0.50 is considered a medium effect size, the trial is well-powered to detect relatively small effect sizes between the intervention groups for these key outcome measures.

9.3 Semi-Structured Qualitative Interviews

Semi-structured interviews with 40 study participants and 15 Action Wellness providers (physicians, nurse practitioners,

medical social workers, CCRP (case manager and financial manager) will be conducted by the University of Pittsburgh team (PI: Hawk, Project Coordinator and doctoral student) to further contextualize findings from the mediation analysis. Interviews will take place in year 3 of the study, providing sufficient time to contextualize initial findings from the mediation analysis and to provide a large enough pool of participants who have completed 12-month follow-up assessments. Information regarding recruitment methods and confidential nature of data are described in sections 5.2 and 4.2.2.

Semi-structured interview guides will be developed for providers and participants using the theoretical framework described above. A draft of the interview guide is attached as Appendix D. Both sets of interviews will explore factors perceived by providers and participants to contribute to ART adherence, specifically examining for the effects of our hypothesized mediators as shown in Figure 1 (housing stability, retention in care, perception of social support, decreased financial stress, etc.) In addition, we will purposively sample clients for interviews based on their success or lack of success in improving ART adherence as well as improved biological measures. In addition, we will interview control arm participants to gain contrasting information regarding our hypothesized mediators. We also seek to understand participants' acceptance of and satisfaction with CCRP and the degree to which these change over time, given that it is likely that the intervention will become easier for clients after an adjustment period is over. Additional information regarding recruitment for qualitative interviews and confidentiality of qualitative data is documented in sections 5.2 and 4.2.2 respectively.

Our sampling approach for qualitative interviews will enable us to assess the degree to which the intervention contributed to adherence changes, as well as mechanisms underlying change. One-on-one interviews will be held in a private space, last 60-90 minutes, and will be audio recorded and professionally transcribed. Participants will receive \$40 in incentives via gift cards to honor their time. Interviews will be digitally recorded and transcribed. Content will be analyzed in NVivo 11 using contextualizing and categorizing strategies. First, the interviews will be explored for major themes to contextualize the data. Then we will develop a set of analytic codes, derived from the exploration of themes as well as a priori hypotheses. All of the interviews will be coded, and at least five interviews will be coded by two researchers and compared for consistency. Results will be discussed with the research team to triangulate and validate the findings.

9.4 Economic Analysis

We will assess the cost, cost threshold, and cost-utility of the CCRP model (Aim 3). This will be accomplished by conducting an economic analysis to estimate the cost of delivering services and the cost thresholds for cost-effectiveness and cost savings. We will also determine if the intervention is cost-effective. The University of Pittsburgh will manage transfer of de-identified data from the study site to researchers from Johns Hopkins Bloomberg School of Public Health, who will conduct a cost-effectiveness analysis. The cost-effectiveness analysis will use de-identified data from the study site including those collected via participant self-report (time spent by clients traveling to and from services, transportation costs to and from services, and HIV risk behavior) as well as those abstracted from the study site, (number of participants enrolled, number of client contacts, time spent by clients in service, wage level for clients, staff personnel costs, materials and consumables, and viral suppression.)

The cost analyses will estimate the cost of delivering the program locally and will be conducted from both the payer perspective (the cost to the party implementing the program, Action Wellness), and the societal perspective (the cost to the party implementing the program + the cost to the participant for participating in the program). The cost analysis will calculate the overall cost of implementing the program, the cost per client, and the cost per contact. The threshold analysis will assess two things: 1) the number of quality-adjusted life years (QALY) that would need to be averted to make a claim of cost-effectiveness, and 2) the number of HIV transmissions that would need to be averted to make a claim of cost savings. The cost-utility analysis will use outcomes data on viral suppression to model whether the

programs are cost effective. As part of sensitivity analyses, we will also conduct the cost-utility analyses using data on adherence to ART.

We will employ standard methods of cost analyses, as recommended by the U.S. Panel on Cost-effectiveness in Health and Medicine and as adapted to HIV/AIDS programs by Holtgrave (80). As such, we will conduct our analyses from the societal perspective as well as the payer perspective. Including the societal perspective accounts for costs to all parties, acknowledges the value of competing uses for societies' resources, and maximizes comparability with other cost-effectiveness analyses.

To conduct the cost analysis and the cost threshold analyses, data will be collected in the following five areas: Step 1: The time period for the analysis; Step 2: A description of the services delivered by the program; Step 3: Summary participant data including number of PLWHA served, number of participant contacts, and costs to the individual for participating in the program; Step 4: Implementation cost including, staff, materials and other consumables; and Step 5: The overhead rate. Step 5 will be optional as it allows for an alternative mechanism to capture data on costs included in Step 4. Step 3 will be used to calculate the cost of the program from the societal perspective. While there will be no fee for participating in the program, we want to account for costs accrued by participants with regard to transportation to and from program services, participants' time, and costs incurred by the participant for dependent care. Data will be entered into a standardized excel spreadsheet which will be organized by the five steps outlined above with embedded formulas to calculate the cost. The investigators have used this methodology for economic analyses for a variety of HIV prevention interventions including a housing intervention for PLWHA.

Data will be collected using three methods: extraction from accounting records, budget records, and dosage forms; interviews with program implementers; and self-report from participants. Participants will self-report data collected in Step 3 on travel time to and from program services, the cost of travel, and dependent care. Data for Step 4 will primarily be collected from existing budgets and accounting records. Data on the number of clients enrolled, and the number of client contacts will be collected from existing participant contact forms.

The time period for the analysis will be six months. As discussed above, the cost of the program will be calculated from data collected in Steps 3, 4, and 5 described above. Specifically, the total costs to the participant will be added to the sum of the implementation costs times one plus the overhead rate ($C = \text{total participant cost} + (\text{implementation costs} * (1 + \text{overhead rate}))$). To calculate the cost-saving threshold, we will use the following formula: C/T where T is the medical costs averted each time a HIV transmission is averted. T will come from the most recent literature. The cost-effectiveness threshold will be calculated using the formula $C/(T + (W * Q))$ where W is the price that society is willing to pay to "buy" a QALY and Q is the number of quality-adjusted life years saved for each HIV transmission averted. Like T, W and Q will be obtained from the most recent literature at the time the analysis is completed. Currently, T is estimated to be \$330,000 (85) W is estimated to be \$100,000, (86-88) and Q is estimated to be about 5.83.

For the cost-utility analysis we will assess whether the program is cost-effective by calculating the cost-utility ratio, or "r". The formula for the cost-utility ratio is $R = (C/A - T)/Q$. C, T, and Q are the same parameters as described above. "A" is the number of HIV infections averted by the program. "A" will be estimated by taking the product of three parameters: a) the difference between those who were and were not exposed to the program in the possibility of HIV transmission b) the average number of sexual behavior partners per year for participants and c) the literature-based average probability of HIV transmission per partnership. The first of these three parameters will be estimated using data on viral suppression (and adherence) for individuals enrolled in the study. The second parameter will be estimated based on self-report data on sexual behavior from participants. The third parameter will be based on the HIV transmission literature. For the sensitivity analyses, we will use an estimate of the number of person-years of adherence among program participants and the difference in HIV transmission rates among those who are and are not adherent to ART to model the number of transmission that were averted as a result of adherence.

10.0 Quality Assurance and Quality Control

10.1 Study Oversight

The PI will be responsible for the oversight and conduct of the study. She will direct the overall performance of this study and maintain responsibility for overall fiscal and research administration. In addition, she will meet with the data management team on a biweekly basis to address issues related to study design, data collection, and analysis. She will travel to the intervention site on a regular basis throughout the study period to support implementation and data collection efforts, as well as to assist with troubleshooting barriers as they arise. The PI will oversee expenditure of grant funds; track spending on this account on a quarterly basis; hire personnel in Pittsburgh; and directly supervise the Graduate Student Researcher and Research Coordinator. She will also be responsible for the development of consent and assessment tools and facilitating collaboration coinvestigators. In addition, with support from a Graduate Student Researcher and the Research Coordinator, she will complete qualitative interviews and analyses with intervention staff as well as with study participants. She will oversee development of research products from this study, including preparing and reporting all presentations and manuscripts in collaboration with the co-investigators.

The PI will serve as the liaison between the study team members, participating sites, and the IRBs of the University of Pittsburgh and City of Philadelphia Department of Health. She will coordinate approval of the initial protocol as well as any subsequent amendments. It is the responsibility of the PI to ensure that the sites are using the correct version of the protocol. This will be accomplished by ensuring that all members of the site team have completed human subjects training, are adequately trained on the approved protocol, study procedures, serious and adverse events reporting, and data collection procedures before the initiation of the recruitment period. We have built a 6-month startup period into our study to ensure that team members will be fully informed of study procedures and requirements before any research begins. The PI will also maintain responsibility for providing updates to and receive feedback from the DSMB as well as for registering the study on clinicaltrials.gov.

10.2 Staff Training

10.2.1 CCRP Fidelity

The study will build on the expertise of The Open Door, Inc. (TOD), the organization that developed the intervention and has successfully provided this service for the past nine years, to ensure that critical elements are deployed in a manner consistent with previous success. In addition to developing this intervention, TOD has provided capacity building assistance to three other organizations that are building their own CCRP programs to improve clinical outcomes for PLWHA who are unstably housed.

Specifically, TOD will support Action Wellness by (a) helping staff members to develop methods of delivering the intervention in accordance with principles of client-centered care; (b) providing pre-intervention training and ongoing coaching to ensure accurate uptake and for problem-solving, including training on SSA policies and procedures, as well as setting up electronic banking for multiple clients; and (c) evaluating and providing feedback regarding staff activities throughout the study period. TOD representatives will be available through the study period to problem-solve, provide feedback, and refine the approach as needed. The PI and Co-Investigators will track process measures to ensure intervention milestones are being met, including organizational appointment as representative payee by SSA, number of participants recruited and engaged, and accurate and timely data collection. This process will not only ensure effective implementation but will also provide a blueprint so that other organizations can replicate CCRP.

10.2.2 Visits to Site

Given that the study site is removed from the study coordinating center, we have dedicated travel funds to ensure on-site presence from Dr. Hawk and co-investigators. In addition to tracking study progress, frequent visits to Action Wellness will ensure the study investigators are able to benefit from the expertise and lessons learned of the clinical providers, medical case managers, and other members of the Action Wellness research team.

Specifically, we have budgeted funds to cover the costs of the PI (Hawk) to travel to Philadelphia to meet with the Co-PI (Hagan) and the Action Wellness research team to discuss study design and start-up in Year 1, and in subsequent years to discuss study progress, troubleshoot issues that arise, as well as to coordinate the analysis plan, study findings, interpretation, and dissemination of results.

In addition, travel costs have been budgeted for Dr. Davis and Ms. Farmartino (from The Open Door) to travel to Philadelphia to provide capacity building assistance in years 1-4 of the study, and for Dr. Brooks and Ms. Martin (from the Epidemiology Data Center) to travel to the intervention site to develop study design, data collection methods, and analysis (Table 4.) In months when investigators do not travel to Philadelphia, the team will meet via Skype or conduct telephone calls twice per month for study updates, and will also be available on demand when questions or issues arise.

Table 4. Visits to Clinical Site

	Year 1	Year 2	Year 3	Year 4	Year 5
Hawk	16	12	6	6	6
Davis	9	4	2	2	
Farmartino	9	4	2	2	
Brooks	2				2
Martin	2				2
Total	40	20	10	10	10

Additional travel costs have been budgeted to coordinate travel as needed for Dr. Brooks and members of the Epidemiology Data Center to visit Action Wellness to coordinate data collection efforts as needed.

11.0 Conflict of Interest

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the trial.

APPENDICES

Appendix A. Data Security Assessment Form

Principal Investigator: Mary Hawk

IRB#: PRO17080613

Investigators must complete this form when data is collected, transmitted, or stored electronically. Upload the completed form into Section 5, question 5.15 of the IRB application or in the Supporting Documentation section if the upload button is not available. We highly recommend the [Data Security Guidance](#) document available in the A-Z Guidance of the HRPO website be reviewed before answering the questions. The IRB may request a consultation from data security experts from either Pitt or UPMC to ensure risks to research participants are minimized and appropriate safeguards are in place. **It is important that all relevant questions are addressed to prevent a delay in review.** If you have any questions, email us at irb@pitt.edu.

- It is important to remember that the research data belongs to the University of Pittsburgh
- All purchase agreements should be processed by the University Purchasing Office. Contact the Pitt Purchasing Office at 412-624-3578 or <http://cfo.pitt.edu/pexpress/CustomService/inquiry.php>

Part A – Identifiers to be collected (check all that apply):

Resource: <http://technology.pitt.edu/security/security-guideline-de-identifying-health-information>

<input type="checkbox"/> Anonymous data – at no time will any identifiers be collected including IP addresses	
Check all identifiers that will be collected below: <small>(If any identifiers will be collected, a data security review may be required)</small>	
<input type="checkbox"/> Name <input type="checkbox"/> Electronic mail address <input type="checkbox"/> Social security number <input type="checkbox"/> Telephone number <input type="checkbox"/> Fax number <input type="checkbox"/> Internet protocol (IP) address <input type="checkbox"/> Medical record number <input type="checkbox"/> Device identifiers/serial numbers <input type="checkbox"/> Web Universal Resource Locators (URLs)	<input type="checkbox"/> Biometric identifiers, including finger and voice prints <input type="checkbox"/> Full face photographic images and any comparable images <input type="checkbox"/> Health plan beneficiary numbers <input type="checkbox"/> Account numbers <input type="checkbox"/> Certificate/license numbers <input type="checkbox"/> Vehicle identifiers and serial numbers, including license plate numbers
Certain dates, age, zip codes or other geographic subdivision that could be personally identifiable per the standards below.	
<input type="checkbox"/> All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes.	
<input checked="" type="checkbox"/> All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older	
<input checked="" type="checkbox"/> List any other unique identifying number, characteristic, or code to be collected: Identifiers are only collected at the study site and will not be collected at study center. Because interviews could potentially include identifiable data, these will be recorded on an Olympus DS-3500 portable recorder with 256-bit file encryption and device PIN locking to ensure data security. Once interviews are complete, any identifying information will be deleted from these files, and the audio tapes will	

be transferred to a Pitt Desktop for transcription using local transcription software. No identifiable data will be transcribed, and once transcription is complete the audio recording will be deleted. Qualitative analysis will therefore be limited to de-identified data.

(DSR required if any identifiers checked above and data is not coded)

For **ALL** of the identifiable data collected above, will you be coding the data by removing the identifiers and assigning a unique study ID/code to protect the identity of the participant? Yes No

Indicate how the coded data will be stored separately from the identifiable data: The dates collected will not be stored separately from other study data. Participants will be assigned a unique study ID at time of randomization. Only authorized site personnel will be able to link study ID to participant name.

Will you be collecting any **sensitive data**? Yes No (DSR required if identifiable, limited data set, or coded sensitive data)

Data is considered to be sensitive when the disclosure of identifying information could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.

Part B – What technologies will be used to collect data?

Mobile App Not applicable

(DSR required)

1. Name of the app:
2. Identify the mobile device platform(s) (IOS/Android/Windows) to be used:
3. Identify who created the app:
4. Whose device will be used: Personal phone Researcher provides phone
5. Address how the app is downloaded to the device:
6. Will data be stored on device for any period of time? Yes No
 - a. If yes, please describe (e.g. queue on phone and then transmit to server, stored on device indefinitely)?
 - b. Is the data encrypted on device? Yes No
7. How is the app secured on the device:
 - a. Is a password or PIN for app required? Yes No
 - b. Is a password or PIN for the device required? Yes No
8. Will the app be able to access other device functionality such as Location, Contacts, Notifications, etc.?
9. Where is data transmitted by device?
 - a. How is it encrypted in transit?
10. Address how the data is coded:
 - a. Are phone numbers or mobile identification numbers stored with data: Yes No
11. When data is transmitted from the device, please list all locations where it will reside (even temporarily):
12. Provide any additional information:

Web-based site, survey or other tool Not applicable

(DSR required except if all data recorded is anonymous)

You select any of the first 4 options, jump to question 6:

Pitt licensed Qualtrics CTSI REDCap

WebDataXpress TrialSpark

If Other, you are required to answer all 8 questions below:

1. Name the site you are using:
2. Who created the site, survey or tool?
3. Where is it hosted:
4. What version of the software is being used, if applicable?
5. How is the data encrypted:
6. Is informed consent being obtained using the same site? Yes No
 - a. If yes, how is re-identification prevented:
7. Once collection is complete, how will you access the data: Data will be exported to a Pitt server and will be accessible to Epidemiology Data Center (EDC) study personnel via an internal network.
8. Does the technology utilized allow for the explicit exclusion of the collection of Internet Protocol (IP) address of the participant's connection? Yes No

If Yes, will you utilize this option to exclude the collection of IP addresses? Yes No
9. Provide any additional information: REDCap forms will be used to return the randomization arm. In addition, REDCap forms will be developed for participants to complete surveys at the study site and study site personnel will complete REDCap forms to document study inactivations, off protocol events and adverse events.

Wearable Device Not applicable

(DSR required except if all data recorded is anonymous and device registered by research team)

* Also complete the mobile app section above if a mobile app will be used with the wearable device

1. Name of device:
2. Is wearable **provided** by participant or research team: Personal device Researcher provides device
3. Is wearable **registered** by participant or research team: Participant registers device Researcher registers device
4. Where is data transmitted by device:
 - a. How is it encrypted in transit:
5. How is data coded:
 - a. Are phone numbers or mobile identification numbers stored with data?
 - b. Will GPS data be collected to identify locations?
6. When data is transmitted from the device, please list all locations where it will reside (even temporarily):
7. Provide any additional information:

Electronic recording or conferencing Not applicable

(DSR required)

1. Describe the method of capturing the image, video, or audio: portable digital recorder
2. Will the images, video, or audio be transmitted over the internet? Yes No
3. How will the images, video or audio be secured to protect against unauthorized viewing or recording: An Olympus DS-3500 portable recorder with 256-bit file encryption and device PIN locking will be used to record the semi-structured interviews (n=55 including participants and providers).
4. Provide any additional information: The audio recording will be transferred to a Pitt desktop, which utilizes encryption software, where it will be transcribed. No identifiable information will be included in the transcripts. The

audio recording will be permanently erased from the portable recorder once transcription is complete and verified. No identifiable information will be included in the transcription or in the qualitative analysis.

Text messaging Not applicable
(DSR required)

1. Are you using the current text messaging available on the device or a separate application:
 - a. If the latter, ensure mobile app section above is completed.
2. Whose device will be used: Personal phone Researcher provides phone
3. What is the content of the messaging:
4. Will messages be limited to appointment reminders? Yes No
5. Is the communication one-way or two-way:
6. Is any other technology being used to collect data? Yes No
 - a. If Yes, describe:
7. Provide any additional information:

Part C - Once data collection is complete, where will it be transmitted, processed, and stored

- If sharing data outside Pitt/UPMC, contact the Pitt Office of Research at <http://www.research.pitt.edu/> as a Data Use Agreement or Contract may be required

1. Server
 - Pitt CSSD NOC Managed Server
 - Pitt Department Managed Server
 - UPMC Managed Server
 - Other (describe):
2. Cloud File Storage
 - Pitt Box
 - Pitt OneDrive/SharePoint Online
 - UPMC My Cloud
 - Other (describe):
3. Workstation
 - Pitt owned desktop or laptop UPMC desktop or laptop Personal desktop or laptop
 - Is encryption used to protect the data when stored on workstation? Yes No
 - If Yes, what product is used to encrypt data? BitLocker Drive Encryption
 - Is anti-virus software installed and up to date? Yes No If Yes, what product and version? Symantec Endpoint 12.1.7061 MP6

Is the operating system kept up to date with Windows or Apple updates? Yes

4. Third-party collaborator or sponsor:
5. Provide any additional information: Data abstracted from participant records at the study site will be transferred to the EDC via Pitt Box and then stored on a Pitt server along with the self-report data. Pitt Box will only be used as the transfer method with data being removed within 24 hours. In addition, Pitt Box will be used to transfer de-identified data to Johns Hopkins Bloomberg School of Public Health for the economic evaluation. The semi-structured interview data (40 participants and 15 providers) will be maintained and analyzed on a Pitt desktop with encryption and anti-virus software and may be merged with select participants' self-report variables. These are the only study data that will be stored on a workstation due to the nature of the semi-structured interview data and the analyses required.

Part D - During the lifecycle of data collection, transmission, and storage

(DSR required if identifiable, limited data set, or coded data is shared with external site)

1. Who will have access to the data: Project personnel in the EDC will have access to the study data, excluding the semi-structured interview data. Designated study personnel at Johns Hopkins Bloomberg School of Public Health will receive de-identified data for the economic evaluation. The semi-structured interview data will only be accessible to Dr. Hawk and her research assistant via a Pitt workstation.
2. How will that access be managed: Access to data on EDC servers is managed by EDC server administrators. Study data will be stored on an EDC SQL Server that is behind the University of Pittsburgh enterprise firewall system and is protected in a server VLAN. Direct access to this database server is not open to anyone outside the EDC. To access these data, researchers will be required to authenticate using their Pitt or EDC credentials. User roles within the project itself that dictate whether a researcher has read and/or write access to the data are granted/denied using corresponding SQL Server roles.
3. Who is responsible for maintaining the security of the data: EDC IT personnel are responsible for the security of the self-report and abstracted data. Department of Behavioral and Community Health Services IT personnel will be responsible for the security of the semi-structured interview data. Mary Hawk, the PI, will also be responsible for data security and approving user access to study data.
4. Describe your reporting plan should your electronic data be intercepted, hacked, or breached (real or suspected): Potential security breaches will be reported to the Pitt and study site IRBs as appropriate.
5. Describe what will happen to the electronic data when the study is completed as University policies require that research records be maintained for at least 7 years after the study has ended: Data will be archived and removed from the server. The archived data will be encrypted and stored at an off-site facility.
 - a. If children are enrolled, provide your plan for ensuring that the records will be retained until the child reaches the age of 23, as required by University Policy:
6. Is this a data coordinating center application? Yes No (If Yes, DSR required)
7. Is this a coordinating center application and response to CC2.8 is YES? Yes No (If Yes, DSR required)
8. Provide any additional information:

I certify I have reviewed and am in compliance with the **terms of service** for all technologies to be used for research activities: Yes N/A as no third party technologies are being used

Appendix B. Participant Consent



Consent to Participate in a Research Study

IMPACT OF REPRESENTATIVE PAYEE SERVICES ON ART ADHERENCE AMONG
MARGINALIZED PEOPLE LIVING WITH HIV/AIDS

PRINCIPAL INVESTIGATOR

Mary Hawk, DrPH, LSW
Assistant Professor
University of Pittsburgh Graduate School of
Public Health
4136 Parran Hall – 130 DeSoto Street
Pittsburgh, PA, 15261
412-648-2342
mary.hawk@pitt.edu

CO-INVESTIGATOR

Elizabeth Hagan, MEd
Deputy Executive Director
Action Wellness
1216 Arch Street, 6th Floor
Philadelphia, PA 19107
215-981-3359
Fax: 215-558-6617
BHagan@actionwellness.org

You can talk to the people who are running this study if you have any questions or worries about being part of it. You can call Mary Hawk at 412-648-2342 or Beth Hagan at 215-981-3359.

The National Institute of Mental health provided the funding for this study.

PURPOSE OF STUDY

The University of Pittsburgh is doing a study to understand how Representative Payee (“Rep Payee”) may help people living with HIV/AIDS to take their medications. We know that people who have trouble paying their bills on time or who do not have stable housing can feel stressed. This stress may make it hard for them to focus on their health. We want to know if helping people to pay their bills on time through a Rep Payee can help them to be healthier.

You are being asked to be part of this study because you:

- Are living with HIV/AIDS
- Speak English or Spanish
- Are 18 years old or older
- Get Social Security (SSI and/or SSDI)
- Do not have a Rep Payee now and have not had one in the past year
- Make less than \$16,642 every year
- Sometimes have trouble taking your medications on time

About 320 people will be a part of this study and it will last for 5 years. If you are in the study you will only be a part of it for 1 year. We will also keep track of your HIV viral load, CD4 counts, and the number of times you go to your doctor for the year after you finish being part of the study. We will do this through the services you already get at Action Wellness. No new lab work will be done.



Your case manager may talk to you about whether or not you can be and want to be in this study. Before you answer you can talk to a different case manager or provider who is not a part of the study. You can also talk to someone else about this study even when you are in it. Action Wellness can help you find someone to talk to who is not a part of the study. You don't have to be a part of any study offered by any of your providers.

RESEARCH ACTIVITIES

This study is for people who believe that they are having a hard time managing their money and that having a Rep Payee would help them be healthier. The Rep Payee service we will provide is a little different from other Rep Payee services. You will make decisions about how your money will be used and someone else will take care of paying your bills. If you want to be in the study, you will be randomly placed in a group. This means that you will not get to pick your group. You could be in the A Group or B Group.

A Group

If you are in the A Group, you will keep getting your normal services at Action Wellness. We will also work with the Social Security Administration (SSA) to see if you qualify for Action Wellness to serve as your Rep Payee. You will be asked to sign a form telling SSA that you have a hard time managing your money and that having a Rep Payee would help you be healthier. The form will also show that you want Action Wellness to be your Rep Payee. This means they will pay your bills for you. Your doctor will also need to sign this form if they agree that having a Rep payee would help you. We cannot promise that SSA will agree to have Action Wellness be your Rep Payee. If for some reason your doctor or SSA does not agree that you need a Rep Payee, you can still stay in this study but will not receive Rep Payee services from Action Wellness.

If SSA approves Action Wellness as your Rep Payee they will open a bank account for you. Your SSI and/or SSDI checks will go straight into that account. You will not have access to the account. The account will only be able to be used for you and to pay your bills. You will work with a case manager at Action Wellness to decide what bills should be paid first. Only you can decide which bills get paid. The money left will be put onto a debit card for you. You will decide how often you want to have this money put on your card. This could be once every week or once every month. You will still get the same amount of money from Social Security as you do now. If you do not want that money to be put on a debit card you can also get it as cash.

You will also be asked to fill out surveys on a computer tablet. You will be asked to fill out this survey when you agree to be in the study. You will be asked to fill out the survey again 3, 6, and 12 months later. You will also be asked to fill out a "mini survey" during months 1 and 9 of the study. All of the surveys you will fill out will give you a special ID number and will not ask for your name. Your name will not be shared with the researchers and no one will ever know what you answered on the forms.

When your one year in the study is over, you can keep Action Wellness as your Rep Payee for free if you want to. If you no longer want Action Wellness to act as your Rep Payee and you feel you can pay your bills without this help, we will help you complete the forms to have SSA remove Action Wellness as your Rep Payee. This is what will happen:

- Your case manager at Action Wellness will write a letter to your doctor explaining why you feel you no longer need a Rep Payee. If your doctor agrees they will sign a form telling SSA they think you no longer need a Rep Payee. If your doctor does not agree and you still do not want a Rep Payee there are other options. Your case manager can work with another doctor to explain why you don't need a Rep Payee. If that doctor agrees you can manage your money on your own they may sign off on the form. Your case manager can also write a letter directly to SSA to tell them why you no longer need these services.



However, just as we cannot be sure that SSA will agree to give you a Rep Payee, we cannot promise that SSA will remove Action Wellness as your Rep Payee.

- If SSA does not agree to have Action Wellness removed as your Rep Payee we will continue to help you through the process. We can get you free services from a lawyer to help you appeal this this decision.
- We can also help you find someone else to be your Rep Payee if you decide that is what you want.

B Group

If you are in the B Group you will keep getting your normal services at Action Wellness. The study will not give you a Rep Payee. The only thing that will be new for you is that you will be asked to complete surveys on a computer tablet. You will be asked to do this when you agree to participate in the study. You will be asked to fill the survey again 3, 6, and 12 months later. You will also be asked to do mini surveys 1 and 9 months into the study. All of the surveys you will fill out will have a special ID number and will not ask for your name. Your name will not be shared with the researchers and no one will ever know what you answered on the forms.

If you are in the B Group you can decide if you think you need help from a Rep Payee after your 12-month in the study is over. Action Wellness will act as your Rep Payee for free. To do this, you will complete a form telling SSA that you want Action Wellness to be your Rep Payee, which means they will pay your bills for you. Your doctor will also need to sign off on this form and agree that you would benefit from this service. At that point, SSA will decide whether or not Action Wellness can be your payee. We cannot promise that SSA will agree to have Action Wellness be your Rep Payee. If for some reason your doctor or SSA does not agree that you need a Rep Payee, you will not receive Rep Payee services from Action Wellness.

Interviews

Forty people who are in the study will be invited to talk with researchers about how they feel about the study and how they felt about Rep Payee. If you are asked and agree to an interview, your case manager will set up a time for you to talk to the researchers. Action Wellness will tell the researchers what your HIV viral load and CD4 counts are. They will also tell the researchers how many times you are able to make your doctors' visits. This will help the researchers think about what questions to ask you. Before you do an interview you will be asked to sign a different consent form. That form will explain how your health information will be shared with the researchers.

If you do an interview with the researchers it will take place at Action Wellness. Your name will not be given to the researchers. The researchers will not tell Action Wellness or anyone else what you say in your interview. If you want to be a part of the study but do not want to talk with the researchers, that is okay. It also means that the researchers will never know your name or be able to identify you.

Rep Payee Responsibilities and Duties

If Action Wellness is your Rep Payee at any time they will do the following things for you:

- Your case manager will meet with you regularly to understand your needs and help you make a budget. You will work with your case manager to decide how you want your bills to be paid, how you want your extra money given to you, and if you want to set up a way to start saving money.
- Your case manager and Action Wellness will make sure that your money is used for your benefit.



- Action Wellness will keep all records of how your bills are paid to help provide an accurate report to SSA when they ask for that.
- Action Wellness will complete forms required by SSA.
- Action Wellness will report things that may affect the amount you are paid (including death or being in prison).
- Action Wellness will follow all other rules as set by SSA. Your case manager can give you a printed copy of these rules before deciding to be in this study or at any time during this study if you would like one.

STUDY RISKS

This study has few risks for people who are in it. Some questions on the survey, like those about sex and drug/alcohol use, can make some people uncomfortable. Action Wellness has people who can talk to you if you feel upset by these questions. It is also important to know that you will not write your name on the survey so no one will ever know how you answer the questions.

Another risk is that some people might feel uncomfortable because their money will be handled by a Rep Payee. This risk is low because you will always talk with your case manager about what bills get paid. Only you can decide what bills will be paid and when. SSA has a lot of rules about how your Rep Payee has to work for you. This means that your money will be safe and you will be protected from identify theft and fraud.

You can also ask to have Action Wellness removed as your Rep Payee at any time in the study. If you no longer want Action Wellness to act as your Rep Payee and you feel you are able to pay your bills without this help, we will help you complete the forms to have SSA remove Action Wellness as your Rep Payee. Again, we can't promise that SSA will approve Action Wellness to be your Rep Payee, or remove Action Wellness as your Rep Payee if you no longer want that service. However, we have explained the way that works above.

Finally, any study with people has some small risk of "loss of confidentiality." That means that in any study there is a risk of personal information being shared outside of the study. To protect you from this risk, we will only collect information which can not be connected to your name. You will get a special ID number assigned to your study information. The researchers will not know your name or be able to identify you. Even the staff at Action Wellness will never know how you answered questions on the survey. Although the Action Wellness staff will not know how you answer questions on the survey, the tablets are programmed so that staff will be alerted if your answers show that you are thinking about harming yourself. Thoughts of death or suicide must be immediately addressed by Action Wellness staff and/or reported to authorities as required by law.

All materials that have your name on it, like this consent form, will be kept in double-locked filing cabinets or in password protected databases so no one else can ever see your information that is part of this study.

STUDY BENEFITS

Some people may be less worried about their money and may feel it is easier to take their medications if they get the free Rep Payee services. If you are in Group B, you can choose to apply for free Rep Payee services after your one year in the study.

This study could help other people living with HIV/AIDS by helping us find a new way to improve their health.



PRIVACY (Person) and CONFIDENTIALITY (Data)

All information in this study will be coded with special numbers. This means that the researchers will not be able to connect your study data to you. However, if you are picked to talk with researchers during the one-on-one meetings, the researcher from the University of Pittsburgh will at Action Wellness. Action Wellness will provide the researcher with your HIV viral load, CD4 count and the number of doctors' visits you were able to attend to help the researcher think of questions to ask you. The researcher will not tell anyone what you say in the interview.

If you want to be in the study but do not want to talk with the researchers during the one-on-one meetings you do not have to. If you are one of those people, the information that is given to the researchers will never have your name on it, just your secret ID number. The researchers will never be able to identify you. No one, even people at Action Wellness, will ever know how you answered the questions on the surveys.

The University of Pittsburgh research team, Johns Hopkins Bloomberg School of Public Health research team, and Philadelphia Department of Public Health Institutional Review Board will be able to see information about people who are in this study. The National Institutes of Health and the University of Pittsburgh Research Conduct and Compliance Office could also look at this information to make sure the study is working as it should. However, these teams will not have access to information that can identify you and or to protected health information. This means that none of these groups will ever be able to connect you to this study. Any information that has your name or identifying information on it will be kept in double-locked filing cabinets at the Action Wellness or in a password-protected database to keep it safe.

The University of Pittsburgh has a policy that states that all research records must be kept for at least 7 years following final reporting of a project. No information that will identify you will be included in these records at any time.

This research is covered by a "Certificate of Confidentiality" from the National Institutes of Health. This means that the researchers can never use information that could identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding. The information you provide cannot be used as evidence in court, even if there is a court subpoena.

Any information about child abuse or intent to harm self or others will be reported to authorities, as required by law.

COMPENSATION

Each time you do a survey about the study on the computer tablet or a "mini check-in" you will receive a \$20 gift card. You will be asked to do the survey on the computer tablet when you join the study and again 3, 6, and 12 months later. You will also be asked to do "mini check-ins" 1 month and 9 months after you join the study. This means you will get a total of \$120 in gift cards if you do the survey and mini check-ins each time. If you are picked to meet with the researcher, you will get another \$20 gift card when you set up the meeting date and another \$20 gift card at the time of the meeting. You get the same amount whether you are in the A Group or the B Group.

FDA CLINICAL TRIAL REGISTRY [21 CFR 50.25]

A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.



questions or talk about your concerns about the study. I further state that no research in this study was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date



Appendix C. Action Wellness Notice of Privacy Practices



Notice of Privacy Practices (NPP) – Full Policy

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

A. Introduction - To our clients

This notice will tell you about how we handle and protect information about you. It tells you how we use this information in our office, in what situations we would share your information with other professionals and how you can see it. Action Wellness personnel include staff, volunteers, and/or contractors who provide you service. We want you to know all of this so you can make the best decisions for yourself. We are also required to tell you about this because of the privacy regulations of a federal law, the Health Insurance Portability and Accountability Act of 1996 (HIPAA). We have a legal duty to protect health information about you.

B. What we mean by your medical information

When you visit Action Wellness or any doctor's office, hospital, clinic or any other healthcare provider, information is collected about you and your physical and mental health. It may be information related to your past, present, or future health or conditions, or the treatment or other service you received from us, or about payment for healthcare. The information we collect from you is called (in the law) **Protected Health Information (PHI)**.

At Action Wellness, PHI is likely to include the following types of information:

- Your history. As a child, in school, and at work, and marital and personal history.
- Confirmation of your HIV+ diagnosis.
- Diagnoses. Diagnoses are the medical terms for your problems or symptoms.
- Treatment Plan or Service Care Plan. These are the treatments and other services which we will work with you to reach your goals for treatment or service.
- Activity Logs. Each time we have contact with you we note the nature of the contact, i.e., phone call, face-to-face visit. We write down some things about what is going on in your life, how you are doing, and what is the next step in the plan.
- Records we get from others who treated you or evaluated you for care.
- Psychological test scores, school records, hospital records, etc.
- Information about medications you are taking or have taken in the past.
- Legal matters
- Benefits and Entitlements information, i.e., SSA, DPW.
- Billing and Insurance Information

C. Privacy and the laws





Notice of Privacy Practices (NPP) – Full Policy

The HIPAA law requires us to keep your PHI private and to give you this notice of our legal duties and our privacy practices which is called the **Notice of Privacy Practices** or NPP. We will follow the rules of this notice, and if we change the rules of the NPP, because the law changes, the rules of the new NPP will apply to all the PHI we keep. If we change the NPP we will post the new Notice in our offices in the lobby. You or anyone else can get a copy of the NPP and it will be posted on our website.

D. Uses and disclosures of PHI in healthcare *with your consent*

After you have read this Notice you will be asked to sign a separate Consent form to allow us to use and share your PHI as specified in this Notice.

We use this information for different purposes. For example, we may use it:

- To plan your care and treatment
- To show that you actually received the services from us for which we billed your health insurance
- For supervision
- To remain in compliance with our funders

When you come to Action Wellness, several people may collect information about you, or need to know who you are. Staff, volunteers, and/or contractors, are included in the definition of Action Wellness. The Consent form you sign allows us to use your PHI for: treatment, for payment, and for healthcare operations.

For Treatment

We may contact you to provide appointment reminders. We may contact you with information about treatment, services, products or health care providers. We may use PHI to manage or coordinate your healthcare. This means telling you about treatments, services, products and/or other healthcare providers.

EXAMPLE: If you are diagnosed with diabetes, we may tell you about other services that may interest to you.

For Payment

We may use your information to bill your insurance company (Medicaid) to be paid for the service we provide to you. We may contact your insurance company to see if a needed service is covered. With your authorization, we may have to tell the insurance company about your diagnoses, and what treatment we are advocating for you for.

For Health Care Operations

The law defines health care operations as including the following:





Notice of Privacy Practices (NPP) – Full Policy

- Reviewing and evaluating the skills, qualifications, and performance of health care providers taking care of you within our organization.
- Providing training programs for students, trainees, health care providers or non-health care professionals (for example, billing clerks or assistants, etc.) to help them practice or improve their skills.
- Cooperating with outside organizations that assess the quality of the care we and others provide. These organizations might include government agencies accrediting bodies such as AACO.

E. Uses and disclosures of (PHI) about you without your authorization or consent

We may use and/or disclose PHI about you for a number of circumstances in which you do not have to consent, give authorization or otherwise have an opportunity to agree or object. Those circumstances include:

- When the use and/or disclosure is required by law. For example, when a disclosure is required by federal, state or local law or other judicial or administrative proceeding.
- When the disclosure relates to victims of abuse, neglect or domestic violence.
- When the use and/or disclosure is for health oversight activities. For example, we may disclose PHI about you to a state or federal health oversight agency which is authorized by law to oversee our operations.
- When the disclosure is for judicial and administrative proceedings. For example, we may disclose PHI about you in response to an order of a court or administrative legislative mandate.
- When the use and/or disclosure relates to decedents. For example, we may disclose PHI about you to a medical examiner for the purposes of identifying you if you should die.
- When the use and/or disclosure is to avert a serious threat to health or safety. For example, we may disclose PHI about you to prevent or lessen a serious and imminent threat to the health or safety of a person or the public.,
- Resolving grievances within our organization involving your complaint.

F. Uses and Disclosure Requiring you to Have an Opportunity to Object

- You have the right to request restrictions on uses and disclosures of PHI about you.
- You have the right to request different ways to communicate with you.
- You have the right to see and copy PHI about you. (we may provide a summary of treatment)
- You have the right to request amendment of PHI about you.
- You have the right to a listing of disclosures we have made.
- You have a right to a copy of this Notice.
- You may file a complaint about our privacy practices.

G. You Have Rights Regarding PHI About You





Notice of Privacy Practices (NPP) – Full Policy

We are not required to agree to your requested restrictions. However, even if we agree to your request, in certain situations your restrictions may not be followed.

For example: You have the right to request how and where we contact you about PHI. You may request that we contact you at your work address or phone number or by email. Your request must be in writing. We must accommodate reasonable requests, but, when appropriate, it will depend on your providing us with information regarding how contact will be handled and your specification of an alternative address or other method of contact. In certain situations, we may not be able to honor your request e.g. emergency treatment, disclosures to the Secretary of the Department of Health and Human Services.

For example: You have the right to request that we make amendments to clinical, billing and other records used to make decisions about you. Your request must be in writing and must explain your reason(s) for the amendment. We may deny your request if: 1) the information was not created by us (unless you prove the creator of the information is no longer available to amend the record); 2) the information is not part of the records used to make decisions about you; 3) we believe the information is correct and complete; or 4) you would not have the right to see and copy the record as described above. We will tell you in writing the reasons for the denial and describe your rights to give us a written statement disagreeing with the denial. If we accept your request to amend the information, we will make reasonable efforts to inform others of the amendment, including persons you name who have received PHI about you and who need the amendment. You may request an amendment of PHI about you by contacting your medical case manager or.

We May Use and Disclose PHI About You *Without Your Additional Authorization* in the Following Circumstances:

- We may use and disclose PHI about you to obtain payment for services.
- Generally, we may use and give your medical information to others to bill and collect payment for the treatment and services provided to you by us.
- Billing departments;
- Insurance companies, health plans and their agents which provide you coverage;
- Assisting various people who review our activities. For example, PHI may be seen by funders reviewing the services provided to you.
- Resolving grievances within our organization.

We may use and disclose PHI under other circumstances without your authorization or an opportunity to agree or object. If it is an emergency-so we cannot ask if you disagree- we can share information if we believe that it is what you would have wanted and if we believe it will help you if we do share it. If we do share information, in an emergency, we will tell you as soon as we can. If you don't approve, we will stop, as long as it is not against the law.





Notice of Privacy Practices (NPP) – Full Policy

**** ANY OTHER USE OR DISCLOSURE OF PHI ABOUT YOU REQUIRES YOUR WRITTEN AUTHORIZATION ****

State law generally restricts our disclosure (and that of your physician) of your health information in most instances. However, we may disclose PHI about you under State law with your permission, pursuant to a court order, or as otherwise permitted or required by law. In instances in which your permission is required, we will request you sign an **Authorization form** (different than the Consent mentioned in other parts of this Notice).

Under any circumstances other than those listed above, we will ask for your written **Authorization** before we use or disclose PHI about you. If you sign a written **Authorization** allowing us to disclose PHI about you in a specific situation, you can later cancel your authorization in writing by contacting your medical case manager. If you cancel your authorization in writing, we will not disclose PHI about you after we receive your cancellation, except for disclosures which were being processed before we received your cancellation.

G. Accounting of Disclosures

You have the right to a listing of disclosures we have made. If you ask in writing, you have the right to receive a written list of certain of our disclosures of PHI about you. You may ask for disclosures made up to six (6) years before your request (not including disclosures made prior to April 14, 2003).

We are required to provide a listing of all disclosures except the following:

- For your treatment
- For billing and collection of payment for your treatment
- Authorized or made by you
- Occurring as a byproduct of permitted uses and disclosures
- Allowed by law when the use and/or disclosure relates to certain specialized government functions.
- As part of a limited set of information not containing certain information which would identify you

The list will include the date of the disclosure, the name of the person or organization receiving the information, a brief description of the information disclosed, and the purpose of the disclosure. If, under permitted circumstances, (in which you have signed a written consent) PHI about you has been disclosed for certain types of research projects, the list may include different types of information. If you request a list of disclosures more than once in 12 months, we can charge you a reasonable fee. You may request a listing of disclosures by contacting your medical case manager in writing.

H. Questions or Problems with NPP





Notice of Privacy Practices (NPP) – Full Policy

You have the right to request a paper copy of this Notice at any time by contacting your medical case manager. We will provide a copy of this Notice no later than the date you first receive service from us (except for emergency services, and then we will provide the Notice to you as soon as possible). You may file a complaint about our Privacy Practices. If you think we have violated your privacy rights, or you want to complain to us about our privacy practices, you can contact the person listed below in writing:

Elizabeth A. Hagan, Director of Client Services
1216 Arch Street 6th Floor
Philadelphia, Pa 19107

215-981-3359
bhagan@actionwellness.org

You may also send a written complaint to the US Secretary of the Department of Health and Human Services. If you file a complaint, we will not take any action against you or change our treatment of you in any way.

Confidential information may be disclosed:

- With the written consent of the client or his or her legally responsible person;
- When in the opinion of a responsible professional there is an imminent danger to the health or safety of the client or other individual or there is the likelihood of the commission of a felony or violent crime;
- When a court orders disclosure;
- For purposes of filing a petition for involuntary commitment, if disclosure is in the best interest of the client, and to courts and attorneys involved in the cases of clients facing court hearings regarding involuntary commitment or voluntary admission;
- For purposes of filing a petition for the adjudication of incompetency of a client, if disclosure is in the best interest of the client;
- To a client advocate providing monitoring and advocacy services to clients of the facility;
- To an attorney who represents the facility or an employee of the facility;
- To researchers if there is a justifiable documented need for the information, and the information will not identify the client;
- To the County Department of Social Services when there is reason to suspect that a child is being abused or neglected, is dependent, or has died as a result of maltreatment;
- To the County Department of Social Services when there is reason to believe that a disabled adult is being abused, neglected, or exploited;
- To a health care provider who is providing emergency medical services to the client;
- Generally, entities and persons receiving confidential information from facilities pursuant to the foregoing provisions are prohibited from re-disclosing the information except as permitted or required by law.

Client Access

We may disclose information to the following people: (i) a health care provider who is providing emergency medical services to you and (ii) to other mental health, developmental disabilities, and substance





Notice of Privacy Practices (NPP) – Full Policy

abuse facilities or professionals when necessary to coordinate your care or treatment. If we determine that there is an imminent threat to your health or safety, or the health or safety of someone else, we may disclose information about you to prevent or lessen the threat. We also will disclose information about you if the law requires us to do so, for example, when a court orders disclosure, when we suspect abuse or neglect of a child or disabled adult. If we believe it is in your best interests, we may disclose information about you for a guardianship or involuntary commitment proceeding that involves you.

Written authorization for the disclosure of records relating to a minor always requires the signature of the minor and, in some circumstances, requires both the signature of the minor and the minor's legally responsible person.

SUMMARY - Client information may be disclosed without the client's authorization:

- To respond to a medical emergency;
- When required by a court order issued in accordance with the regulations;
- To communicate with law enforcement personnel about a crime or threatened crime on the premises of a program or against program personnel;
- As part of a program audit or evaluation activity;
- To comply with state law mandating the reporting of child abuse or neglect.

This Notice of Privacy Practices is effective on April 14th, 2003.





Notice of Privacy Practices (NPP) – Full Policy

This form is an agreement between you, _____ and Action Wellness. In this form “You” includes contact between Action Wellness, yourself, & your alternate contact if you have written his or her name here: _____. ‘We’ will refer to Action Wellness, including staff, volunteers, and contractors.

When we provide service to you, we will be collecting what the law calls Protected Health Information (PHI) about you. This form is specific to the study we are conducting with the University of Pittsburgh. That study is testing the impact of Representative Payee services on medication adherence of people living with HIV/AIDS. You are being asked to complete this form because you have agreed to do a qualitative interview with one of the researchers from the University of Pittsburgh. We will not tell them your name or other identifying information. However, we will share information with them about your CD4 or viral load counts, and how many times you have been able to go to your doctor since being in your study. This information will help the interviewers know what kinds of questions to ask you.

If you agree to do an interview with the researchers it will last about 60 minutes and be audio recorded. The recording is an important way to make sure we understand what you say during the interview. If you do not want to be recorded then you should not do the interview. The interviews will not ask your name or include it in the recording. Once the interview is complete, the recording will be typed up and any information that could identify you will be removed. The recording will then be destroyed. During the time of the research, the audio recordings will be saved on a password protected drive.

By signing this form, you are acknowledging that you have read the Notice of Privacy Practices (NPP) agreement, and that you are agreeing to let us use the information in the manner and extent to which it is explained in the NPP form **and for additional research purposes as described above**. We are required by Federal Law to have a formal Notice of Privacy Practice and to ask you to sign this consent form acknowledging that you have been informed of and agree with the policy. In the future we may change the Notice of Privacy practice. If we do change it, we will inform you, and you can get a copy of the form.

If you are concerned about some of your information being shared in the manner outlined in the Notice of Privacy Practice, you have the right to ask us not to use or share some of your information for treatment, payment, or administrative purposes. You will have to tell us what you want in writing, and though we will do our best to accommodate your request, we are not required to agree to the limitations. We will inform you if this is the case.

After you have signed this consent, you have the right to revoke it, in writing, and we will comply with your wishes about using the information from that time on.

“By signing this consent, I am agreeing that I have been offered a copy of the Action Wellness Notice of Privacy Practice, and I have read the NPP or it has been explained to me, and I understand it.”





Notice of Privacy Practices (NPP) – Full Policy

Please initial your choice:

_____ “I ACCEPT a copy of the NPP.”

_____ “I DECLINE a copy of the NPP.”

Signature of Client Date

Witness Date



Appendix D. Script for Participation: Provider Qualitative Interviews

Impact of Representative Payee services on ART Adherence among Marginalized People Living with HIV/AIDS

Provider Interviews

Script for Participation

The purpose of this research project is to assess the impact of Client-Centered Representative Payee (CCRP) services on marginalized people living with HIV/AIDS. Qualitative interviews with providers are being conducted to understand their perceptions of the impact of CCRP on their clients, to qualitatively assess their experiences with this service, and to contextualize findings from the quantitative analysis of this study. You are being invited to participate in this interview because you provide care or services to participants of the CCRP study, and may have some knowledge regarding how the intervention has affected your clients. Participation in this interview is entirely voluntary, and should you choose not to participate it will not affect your relationship with the University of Pittsburgh or Action Wellness

Risks associated with this study are minimal. Any study with human subjects has some small risk of loss of confidentiality. Your confidentiality will be protected in this study as I will not be attaching your name to any of these notes or to the voice recordings. I want to assure you that only I will be aware of your responses and only I will know who said what. None of your responses will be shared with other staff at Action Wellness and your name will not be attached to this recording. However, any information that is shared about child abuse or intent to harm self or others will be reported to authorities, as required by law. Participation in this interview is voluntary and if you should change your mind at any time during the interview please let me know and we will stop.

If you are interested in participating our interview should take about an hour, depending on how the conversation goes, and it will be recorded on this tape recorder. Later we will transfer this recording to a Pitt desktop, transcribe, and import it into qualitative analysis software. All identifying information will be removed from the transcript prior to coding and analysis. The Pitt desktop utilizes encryption software. The audio recording will be permanently erased from the portable recorder.

There are also no foreseeable benefits for you to participate in this interview. People living with HIV/AIDS may benefit from the study if we identify a new way of offering services to people that help to improve their treatment adherence.

Do you have any questions or comments before we proceed?

Again, I would like to thank you for taking the time to talk with me today.

Mary Hawk
Principal Investigator
412-648-2342

Appendix E. Semi-Structured Interview Protocol (Drafts)

Participant Protocol

Domain: History with Provider

1. Tell me about when you first came to Action Wellness.
 - a. What services do you get here?
2. What are your relationships with your providers like?
3. Are you currently receiving CCRP services?
 - a. Have you ever had a representative payee in the past? Tell me about that.

Domain: Progress with Adherence

4. How easy or hard is it for you to go to the doctor?
5. What about taking your meds?
6. What kind of things help you to take care of your health?
 - a. What kinds of things make it hard to take care of your health?

Domain: Hypothesized Mechanisms of Adherence

7. What makes it hard or easy for you to take your meds as your doctor has instructed you to?

Transition: Sometimes people find other things in their lives affect their abilities to stick with their treatment plans.

8. What is your current housing situation like?
 - a. What, if anything, about the way you live makes it hard for you to take care of your health?
 - b. How has your housing situation changed in the past 12 months?
9. Who do you turn to when you are stressed or worried?
 - a. In what kinds of ways do they help you?
 - b. How involved in your HIV care are they?
 - c. How have these relationships changed in the past year?
10. Let's talk about a little bit about money. How often do you feel stressed about having enough money to do the things you want to do?
 - a. How does this affect your health?
 - b. What do you do when you feel upset about finances?

How has your financial picture changed or stayed the same in the past year?

Domain: Satisfaction with Services

11. For the last part of our talk I'd like to go back to discussing representative payee services. What did you think when you first heard about this study?
 - a. Had you ever heard about representative payee before?
12. [Intervention arm] What has it been like to have a Rep Payee?
 - a. What is good about this service?
 - b. What is bad about this service?
13. [Intervention arm] Has Rep Payee changed anything in your life?
14. [Control arm] Would you ever consider having a Rep Payee?
 - a. What do you think would be good about this service?
 - b. What do you think would be bad about this service?
15. [Control arm] Do you know anyone who has had a Rep Payee?
 - a. Where did they get this service?
 - b. What have they told you about it?

Provider Protocol

Domain: History with Provider

1. Tell me what you do at Action Wellness.
 - a. How long have you worked here?
 - b. What is it like to work here?
2. What are your relationships with your clients like?

Domain: Hypothesized Mechanisms of Adherence

3. What kinds of things make it hard for your clients to come in for care?
 - a. To take their meds as prescribed?
4. What is the relationship between housing and adherence for your clients?
5. What kinds of conversations happen with your clients about money?
 - a. Do these conversations happen a lot?

Domain: Patient Satisfaction with Services

6. What did you think when you first heard about this study?
 - a. Had you ever heard about representative payee before?
7. What have your clients told you about having a Rep Payee?
8. How has this study been for you?
 - a. What has been hard or easy about having the Rep Payee program here?
 - b. How has the program changed things for your clients?
9. What else should we know about the impact of CCRP on your clients?
 - a. What should we be doing differently?

Appendix F. University of Pittsburgh IRB Approval Letter

10/4/2017

<https://www.osiris.pitt.edu/osiris/Doc/0/IV26V45FFHE4NCFPSK30ALC278/fromString.html>



University of Pittsburgh Institutional Review Board

3500 Fifth Avenue
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
<http://www.irb.pitt.edu>

Memorandum

To: Mary Hawk , PhD
From: IRB Office
Date: 10/4/2017
IRB#: [PRO17080613](#)
Subject: Impact of Representative Payee Services on ART Adherence Among Marginalized People Living with HIV/AIDS (Central IRB: 1 R01 MH112416-01A1)

The University of Pittsburgh IRB is acting as the IRB of Record for Action Wellness for this particular research study.

The University of Pittsburgh Institutional Review Board reviewed and approved the above referenced study by the expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110. Your research study was approved under:

45 CFR 46.110.(5)
45 CFR 46.110.(6)
45 CFR 46.110.(7)

The IRB has determined the level of risk to be minimal.

The IRB has approved the waiver for the requirement to obtain a written informed consent for all procedures Provider-participants will undergo.

Approval Date: 10/4/2017
Expiration Date: 10/3/2018

For studies being conducted in UPMC facilities, no clinical activities can be undertaken by investigators until they have received approval from the UPMC Fiscal Review Office.

Appendix G. Philadelphia Health Department IRB Approval Letter

OMB No. 0990-0263
Approved for use through 5/6/2021

Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56 FR 23003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule. Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type <input checked="" type="checkbox"/> ORIGINAL <input type="checkbox"/> CONTINUATION <input type="checkbox"/> EXEMPTION	2. Type of Mechanism <input checked="" type="checkbox"/> GRANT <input type="checkbox"/> CONTRACT <input type="checkbox"/> FELLOWSHIP <input type="checkbox"/> COOPERATIVE AGREEMENT <input type="checkbox"/> OTHER: In House	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No. NIH/NIMH 1 R01 MH112416-01A1
4. Title of Application or Activity 8017-67 Impact of Representative Payee Services on ART Adherence among Marginalized People Living with HIV/AIDS		5. Name of Principal Investigator, Program Director, Fellow, or Other Mary Hawk, DrPH, T.S.W. (U Pittsburgh)

6. Assurance Status of this Project (Respond to one of the following)

- This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No. PYAR0003616, the expiration date 12/31/2021 IRB Registration No. IRB00000032
- This Assurance, on file with (agency/dep't) _____, covers this activity.
Assurance No. _____, the expiration date _____ IRB Registration/Identification No. _____ (if applicable)
- No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.
- Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph _____

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

- This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: Full IRB Review on January 30, 2018 and/or Expedited Review on March 28, 2018 and April 6, 2018
 If less than one year approval, provide expiration date _____
- This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	10. Name and Address of Institution Philadelphia Department of Public Health 1101 Market Street, Suite 1320 Philadelphia, PA 19107
11. Phone No. (with area code) 215-685-5244 12. Fax No. (with area code) 13. Email: Raynard.Washington@Phila.Gov	
14. Name of Official Raynard Washington, PhD	15. Title Chief Epidemiologist
16. Signature 	17. Date 04/06/18

Authorized for Local Reproduction Sponsored by HHS

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-0263. The time required to complete this information collection is estimated to average 30 minutes per response. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health and Human Services, 4830 RCGMRA, 20th Independence Ave., S.W., Suite 335-E, Washington D.C. 20201, Attention: PRA Registry Clearance Officer.

April 6, 2018

Mary Hawk, DrPH, LSW
University of Pittsburgh Graduate School of Public Health
4136 Parran Hall, 130 DeSoto Street
Pittsburgh, PA 15261
Meh96@pitt.edu

Re: 2017-67 Impact of Representative Payee Services on ART Adherence among Marginalized People Living with HIV/AIDS

Dear Dr. Hawk:

The City of Philadelphia Department of Public Health Institutional Review Board [OHRP IRB#49, operating under FWA#3616] approved the above subject research proposal through full committee review. Conditional approval was granted on January 30, 2018 and full approval was granted on April 6, 2018. A copy of the assurance/certification form for this project is attached.

Any serious adverse events or protocol violations must be reported to this office within two working days of discovery. Non-serious adverse event should be reported upon your receipt of a DSMB summary report or with your continuing review update report. Changes in investigators, contact information, procedures or consent procedures or forms must be reviewed and approved prior to implementation, except where necessary to eliminate apparent immediate hazards to the human subjects. An update report for continuing review must be submitted and receive continuing IRB approval by April 5, 2019.

If you have any questions, you can reach me at Health Center #5, 1900 N. 20th Street, Philadelphia, PA 19121, phone number (215) 685-0869 or e-mail at Jessica.Robbins@phila.gov.

Sincerely,



Jessica M. Robbins, PhD
Administrator

CC: correspondence file
#2017-67
Coleman Terrell
C. Johnson, MD

Appendix H. DSMB Forms

CCRP Adverse Events Form

Participant ID: _____

Date of Completion: <system date>

Instructions: This form is required for events that are related to a study visit (including events on the Action Wellness premises immediately before and after a visit) OR events that are related to the study intervention, are an untoward or unfavorable medical occurrence for the participant, including any abnormal sign, symptom or disease, and do *not* meet the definition of a Serious Adverse Event.

Date of event onset: ____ / ____ / 20 ____
mm dd yyyy

Date site became aware of event: ____ / ____ / 20 ____
mm dd yyyy

Was this event unexpected (not documented prior to study recruitment as a possible event related to the study visit and/or intervention and is not recognized as part of the natural progression of HIV/AIDs)?

- Expected
- Unexpected

What is the severity of the event? *If the severity is life threatening or results in death, an SAE form (not an AE form) must be completed in the data management system.*

- Mild (easily tolerated condition or symptom)
- Moderate (discomfort interferes with usual activity)
- Severe (incapacitating or causes inability to work or undertake usual activity)

Was the event related to this research study?

- Definitely related (would not have occurred outside of the study visit and/or intervention)
- Probably related (likely to have occurred due to the study visit and/or intervention)
- Possibly related (may have occurred due to the study visit and/or intervention)
- Not related (would have occurred regardless of the study visit and/or intervention)

General description of event:

Action taken. *If the action taken was inpatient hospitalization, an SAE form (not an AE form) must be completed in the data management system.*

- None
- Out-patient evaluation
- Other, specify _____

What is the status of this event?

- Ongoing
- Resolved

Date of resolution ___ / ___ / 20 ___

Reporting

1. Was this AE reported to the Pitt IRB?
 Yes, date reported to Pitt IRB: ___ / ___ / 20 ___
 No, did not meet reporting criteria

2. Was this AE reported to the Philadelphia IRB?
 Yes, date reported to Philadelphia IRB: ___ / ___ / 20 ___
 No, did not meet reporting criteria

3. Date reported to NIMH: ___ / ___ / 20 ___

CCRP Serious Adverse Events Form

Participant ID: _____

Date of Completion: <system date>

Instructions: An adverse event will be deemed a Serious Adverse Event (SAE) if it is fatal or life-threatening; requires or prolongs hospitalization; produces a disability; results in a congenital anomaly/birth defect; or may require medical intervention to prevent any of the preceding.

Date of event onset: ____ / ____ / 20 ____
mm dd yyyy

Date site became aware of event: ____ / ____ / 20 ____
mm dd yyyy

Event Criteria (check all that apply):

- Death
- Life threatening (immediate risk of death)
- Inpatient hospitalization or prolongation of existing hospitalization
- Persistent or significant disability/incapacity
- Congenital anomaly/birth defect
- Other adverse event that may require medical or surgical intervention to prevent one of the above

Was this event unexpected (not documented prior to study recruitment as a possible event related to the study visit and/or intervention and is not recognized as part of the natural progression of HIV/AIDS)?

- Expected
- Unexpected

What is the severity of the event?

- Mild (easily tolerated condition or symptom)
- Moderate (discomfort interferes with usual activity)
- Severe (incapacitating or causes inability to work or undertake usual activity)
- Life threatening
- Death

Was the event related to this research study?

- Definitely related (would not have occurred outside of the study visit and/or intervention)
- Probably related (likely to have occurred due to the study visit and/or intervention)
- Possibly related (may have occurred due to the study visit and/or intervention)
- Not related (would have occurred regardless of the study visit and/or intervention)

General description of event:

Other relevant history, including preexisting medical conditions

What is the status of this event?

- Ongoing
- Resolved

Date of resolution ___ / ___ / 20 ___

- Death

Date of death: ___ / ___ / 20 ___ Unknown

Report Dates

Date reported to Pitt IRB: ___ / ___ / 20 ___

Date reported to Philadelphia IRB: ___ / ___ / 20 ___

Date reported to NIMH: ___ / ___ / 20 ___

5. General description of event:

6. Was corrective action taken required? No Yes

6.1 Specify corrective action taken:

7. What is the status of this event?

Ongoing

Resolved

Date of resolution ___ / ___ / 20 ___

Death

Date of death: ___ / ___ / 20 ___ Unknown

If the event is a Serious Adverse Event, complete the SAE form in addition to this form.

Report Dates:

Date reported to Pitt IRB: ___ / ___ / 20 ___

Date reported to Philadelphia IRB: ___ / ___ / 20 ___

Date reported to NIMH: ___ / ___ / 20 ___

Data Safety Monitoring Minutes Template

Date of Meeting:

Indicate the members of the staff that were present at the meeting:

The following information was discussed at the meeting	
Recruitment and Retention	
Data Issues (timeliness and quality)	
Unanticipated Problems Do these need to be reported to the appropriate oversight agencies (i.e. IRB, FDA, DoD)?	
Adverse Events and Serious Adverse Events Do these need to be reported to the appropriate oversight agencies (i.e. IRB, FDA, DoD)?	
Confidentiality issues	
Change in risk benefit ratio	
Other issues addressed	

Signature Principal Investigator: _____ Date: _____

REFERENCES

1. Kahn JR, Fazio EM. Economic status over the life course and racial disparities in health. *J Gerontol B Psychol Sci Soc Sci.* 2005;60 Spec No 2:76-84. Epub 2005/10/28. PubMed PMID: 16251596.
2. Kahn JR, Pearlin LI. Financial strain over the life course and health among older adults. *J Health Soc Behav.* 2006;47(1):17-31. Epub 2006/04/06. PubMed PMID: 16583773.
3. Szanton SL, Thorpe RJ, Whitfield K. Life-course financial strain and health in African-Americans. *Soc Sci Med.* 2010;71(2):259-65. Epub 2010/05/11. doi: 10.1016/j.socscimed.2010.04.001. PubMed PMID: 20452712; PMCID: PMC2885496.
4. Muthulingam D, Chin J, Hsu L, Scheer S, Schwarcz S. Disparities in engagement in care and viral suppression among persons with HIV. *J Acquir Immune Defic Syndr.* 2013;63(1):112-9. Epub 2013/02/09. doi: 10.1097/QAI.0b013e3182894555. PubMed PMID: 23392459.
5. Bhunu CP. Assessing the impact of homelessness on HIV/AIDS transmission dynamics. *Cogent Mathematics.* 2015;2(1):1021602. doi: 10.1080/23311835.2015.1021602.
6. Milloy MJ, Marshall BD, Montaner J, Wood E. Housing status and the health of people living with HIV/AIDS. *Curr HIV/AIDS Rep.* 2012;9(4):364-74. Epub 2012/09/13. doi: 10.1007/s11904-012-0137-5. PubMed PMID: 22968432; PMCID: Pmc3693560.
7. Lee JO, Herrenkohl TI, Kosterman R, Small CM, Hawkins JD. Educational inequalities in the co-occurrence of mental health and substance use problems, and its adult socio-economic consequences: a longitudinal study of young adults in a community sample. *Public Health.* 2013;127(8):745-53. Epub 2013/07/23. doi: 10.1016/j.puhe.2013.04.005. PubMed PMID: 23870846; PMCID: PMC3810533.
8. Sutin AR, Evans MK, Zonderman AB. Personality traits and illicit substances: the moderating role of poverty. *Drug Alcohol Depend.* 2013;131(3):247-51. Epub 2012/12/26. doi: 10.1016/j.drugalcdep.2012.10.020. PubMed PMID: 23265091; PMCID: PMC3610771.
9. Toumbourou JW, Hemphill SA, Tresidder J, Humphreys C, Edwards J, Murray D. Mental health promotion and socio-economic disadvantage: lessons from substance abuse, violence and crime prevention and child health. *Health Promot J Austr.* 2007;18(3):184-90. Epub 2008/01/19. PubMed PMID: 18201160.
10. Johnson JG, Cohen P, Dohrenwend BP, Link BG, Brook JS. A longitudinal investigation of social causation and social selection processes involved in the association between socioeconomic status and psychiatric disorders. *J Abnorm Psychol.* 1999;108(3):490-9. Epub 1999/08/31. PubMed PMID: 10466273.
11. Cooper HL, Linton S, Kelley ME, Ross Z, Wolfe ME, Chen YT, Zlotorzynska M, Hunter-Jones J, Friedman SR, Des Jarlais D, Semaan S, Tempalski B, DiNenno E, Broz D, Wejnert C, Paz-Bailey G. Racialized risk environments in a large sample of people who inject drugs in the United States. *Int J Drug Policy.* 2016;27:43-55. Epub 2015/09/08. doi: 10.1016/j.drugpo.2015.07.015. PubMed PMID: 26342272; PMCID: PMC4715941.
12. Bangsberg DR, Hecht FM, Charlebois ED, Zolopa AR, Holodniy M, Sheiner L, Bamberger JD, Chesney MA, Moss A. Adherence to protease inhibitors, HIV-1 viral load, and development of drug resistance in an indigent population. *AIDS.* 2000;14(4):357-66. Epub 2000/04/19. PubMed PMID: 10770537.
13. Baum MK, Rafie C, Lai S, Sales S, Page B, Campa A. Crack-cocaine use accelerates HIV disease progression in a cohort of HIV-positive drug users. *J Acquir Immune Defic Syndr.* 2009;50(1):93-9. Epub 2009/03/20. doi: 10.1097/QAI.0b013e3181900129. PubMed PMID: 19295339.
14. Friedman MS, Marshal MP, Stall R, Kidder DP, Henny KD, Courtenay-Quirk C, Wolitski RJ, Aidala A, Royal S, Holtgrave DR. Associations between substance use, sexual risk taking and HIV treatment adherence among homeless people living with HIV. *AIDS Care.* 2009;21(6):692-700. Epub 2009/10/07. doi: 10.1080/09540120802513709. PubMed PMID: 19806485.

15. Knowlton A, Arnsten J, Eldred L, Wilkinson J, Gourevitch M, Shade S, Dowling K, Purcell D. Individual, interpersonal, and structural correlates of effective HAART use among urban active injection drug users. *J Acquir Immune Defic Syndr.* 2006;41(4):486-92. Epub 2006/05/03. doi: 10.1097/01.qai.0000186392.26334.e3. PubMed PMID: 16652058.
16. Buot ML, Docena JP, Ratemo BK, Bittner MJ, Burlew JT, Nuritdinov AR, Robbins JR. Beyond race and place: distal sociological determinants of HIV disparities. *PLoS One.* 2014;9(4):e91711. Epub 2014/04/20. doi: 10.1371/journal.pone.0091711. PubMed PMID: 24743728; PMCID: PMC3990614.
17. Friedman MR, Stall R, Silvestre AJ, Wei C, Shoptaw S, Herrick A, Surkan PJ, Teplin L, Plankey MW. Effects of syndemics on HIV viral load and medication adherence in the multicentre AIDS cohort study. *Aids.* 2015;29(9):1087-96. Epub 2015/04/15. doi: 10.1097/qad.0000000000000657. PubMed PMID: 25870981.
18. Chaiyachati KH, Ogbuaji O, Price M, Suthar AB, Negussie EK, Barnighausen T. Interventions to improve adherence to antiretroviral therapy: a rapid systematic review. *Aids.* 2014;28 Suppl 2:S187-204. Epub 2014/05/23. doi: 10.1097/qad.0000000000000252. PubMed PMID: 24849479.
19. Blankenship KM, Bray SJ, Merson MH. Structural interventions in public health. *AIDS (London, England).* 2000;14 Suppl 1:S11-S21. doi: 10.1097/00002030-200006001-00003.
20. Blankenship KM, Friedman SR, Dworkin S, Mantell JE. Structural interventions: concepts, challenges and opportunities for research. *J Urban Health.* 2006;83(1):59-72. Epub 2006/06/01. doi: 10.1007/s11524-005-9007-4. PubMed PMID: 16736355; PMCID: PMC1473169.
21. Angell B, Martinez NI, Mahoney CA, Corrigan PW. Payeeship, financial leverage, and the client-provider relationship. *Psychiatr Serv.* 2007;58(3):365-72. Epub 2007/02/28. doi: 10.1176/appi.ps.58.3.365. PubMed PMID: 17325110.
22. Rosen MI, Dieckhaus K, McMahon TJ, Valdes B, Petry NM, Cramer J, Rounsaville B. Improved adherence with contingency management. *AIDS patient care and STDs.* 2007;21(1):30-40. doi: 10.1089/apc.2006.0028.
23. Phelan JC, Link BG, Diez-Roux A, Kawachi I, Levin B. "Fundamental causes" of social inequalities in mortality: a test of the theory. *J Health Soc Behav.* 2004;45(3):265-85. Epub 2004/12/15. PubMed PMID: 15595507.
24. Mani A, Mullainathan S, Shafir E, Zhao J. Poverty impedes cognitive function. *Science.* 2013;341(6149):976-80. Epub 2013/08/31. doi: 10.1126/science.1238041. PubMed PMID: 23990553.
25. Conrad KJ, Matters MD, Luchins DJ, Hanrahan P, Quasius DL, Lutz G. Development of a money mismanagement measure and cross-validation due to suspected range restriction. *Journal of Applied Measurement.* 2006;7(2):206-24.
26. Angell B, Martinez NI, Mahoney CA, Corrigan PW. Payeeship, financial leverage, and the client-provider relationship. *Psychiatric Services.* 2007;58(3):365-72. doi: 10.1176/appi.ps.58.3.365.
27. Appelbaum PS, Redlich A. Use of leverage over clients' money to promote adherence to psychiatric treatment. *Journal of Nervous and Mental Disease.* 2006;194(4):294-302. doi: 10.1097/01.nmd.0000207368.14133.0c.
28. Flickinger TE, Saha S, Moore RD, Beach MC. Higher quality communication and relationships are associated with improved patient engagement in HIV care. *J Acquir Immune Defic Syndr.* 2013;63(3):362-6. Epub 2013/04/18. doi: 10.1097/QAI.0b013e318295b86a. PubMed PMID: 23591637; PMCID: Pmc3752691.
29. Vladeck BC, Westphal E. Dignity-Driven Decision Making: A Compelling Strategy For Improving Care For People With Advanced Illness. *Health Affairs.* 2012;31(6):1269-76. doi: 10.1377/hlthaff.2012.0173.
30. Beach MC, Duggan PS, Moore RD. Is clients' preferred involvement in health decisions related to outcomes for clients with HIV? *J Gen Intern Med.* 2007;22(8):1119-24. Epub 2007/05/22. doi: 10.1007/s11606-007-0241-1. PubMed PMID: 17514382; PMCID: PMC2305727.
31. Hawk M, Davis D. The effects of a harm reduction housing program on the viral loads of homeless individuals living with HIV/AIDS. *AIDS Care.* 2012;24(5):577-82. Epub 2011/11/23. doi: 10.1080/09540121.2011.630352. PubMed PMID: 22103666.
32. Marshall BD, Elston B, Dobrer S, Parashar S, Hogg RS, Montaner JS, Kerr T, Wood E, Milloy MJ. The population Impact of eliminating homelessness on HIV viral suppression among people who use drugs. *Aids.* 2015. Epub 2015/12/05. doi: 10.1097/qad.0000000000000990. PubMed PMID: 26636924.

33. Davis D, Hawk M, McLaughlin J, Brincko T, King M, Farmartino C. Despite initial "kicking and screaming" unstably housed persons report high satisfaction with representative payee program. *Housing, Care and Support*. 2015;18(2):56-61. doi: 10.1108/HCS-05-2015-0008.
34. Hawk M, McLaughlin J, Farmartino C, King M, Davis D. The impact of representative payee services on medication adherence among unstably housed people living with HIV/AIDS. *AIDS Care*. 2015:1-6. Epub 2015/10/08. doi: 10.1080/09540121.2015.1093073. PubMed PMID: 26444847.
35. Medicaid and HIV/AIDS. Kaiser Family Foundation.
36. Shah M, Perry A, Risher K, Kapoor S, Grey J, Sharma A, Rosenberg ES, Del Rio C, Sullivan P, Dowdy DW. Effect of the US National HIV/AIDS Strategy targets for improved HIV care engagement: a modelling study. *Lancet HIV*. 2016;3(3):e140-6. Epub 2016/03/05. doi: 10.1016/s2352-3018(16)00007-2. PubMed PMID: 26939737.
37. Yehia BR, Stephens-Shields AJ, Fleishman JA, Berry SA, Agwu AL, Metlay JP, Moore RD, Christopher Mathews W, Nijhawan A, Rutstein R, Gaur AH, Gebo KA. The HIV Care Continuum: Changes over Time in Retention in Care and Viral Suppression. *PLoS One*. 2015;10(6):e0129376. Epub 2015/06/19. doi: 10.1371/journal.pone.0129376. PubMed PMID: 26086089; PMCID: PMC4473034.