

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

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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 sites are Action Wellness, in Philadelphia, PA, The Open Door, in Pittsburgh, PA and Birmingham AIDS Outreach, in Birmingham, AL (referred to going forward as “study sites.”) 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=160) will be randomized to the intervention or the standard of care. An additional 50 participants will be enrolled into the choice arms with 25 in choice intervention and 25 in choice control. Participants in the randomized and choice intervention arms will receive CCRP services for a period of 12 months. We will collect clinical and self-report data for participants in the four 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 the study sites’ patient records. Mixed methods will be used to test our hypotheses, including a mediation analysis, process measures, survey measures, and qualitative interviews with eligible individuals including those that didn’t want to participate in the study. 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

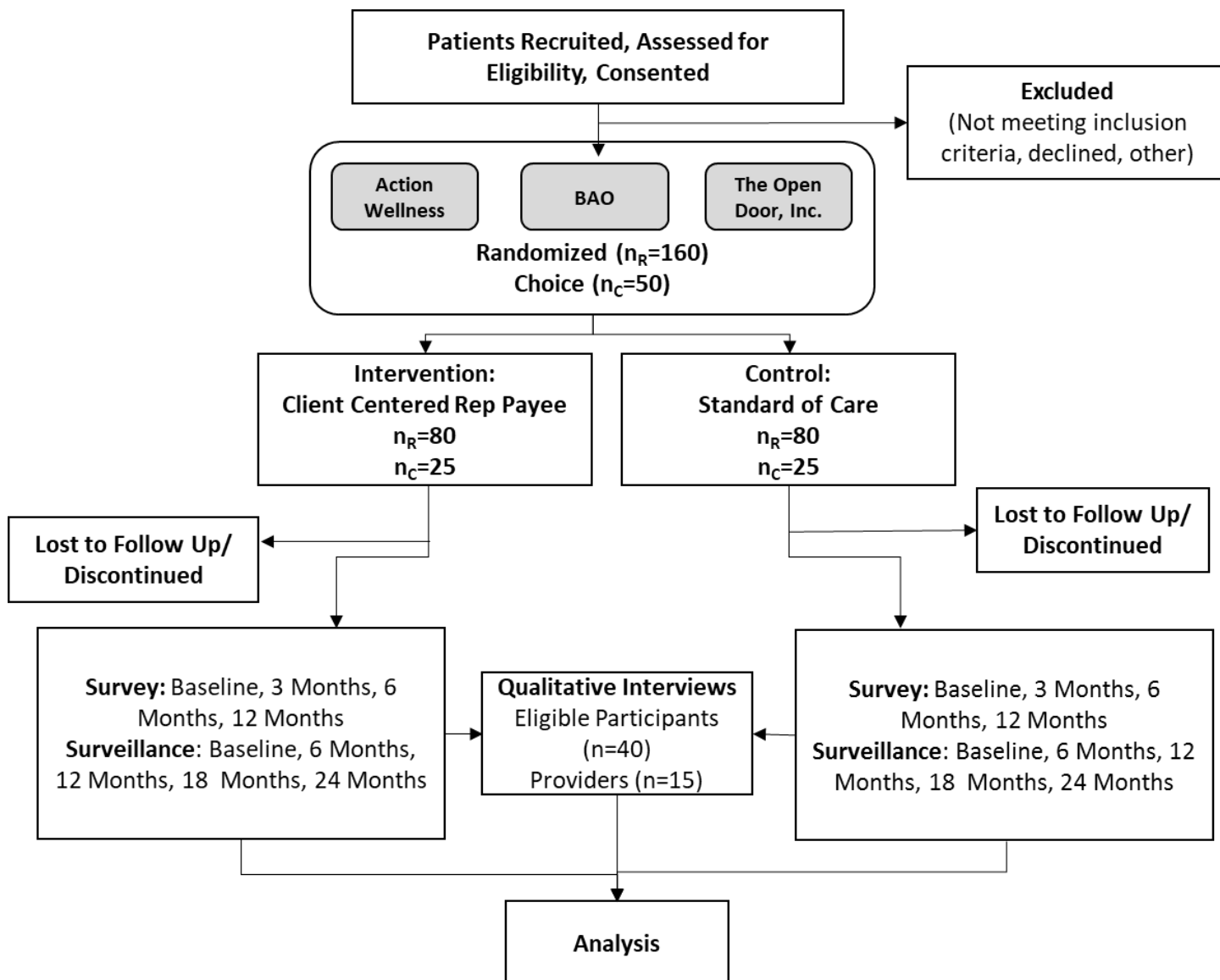
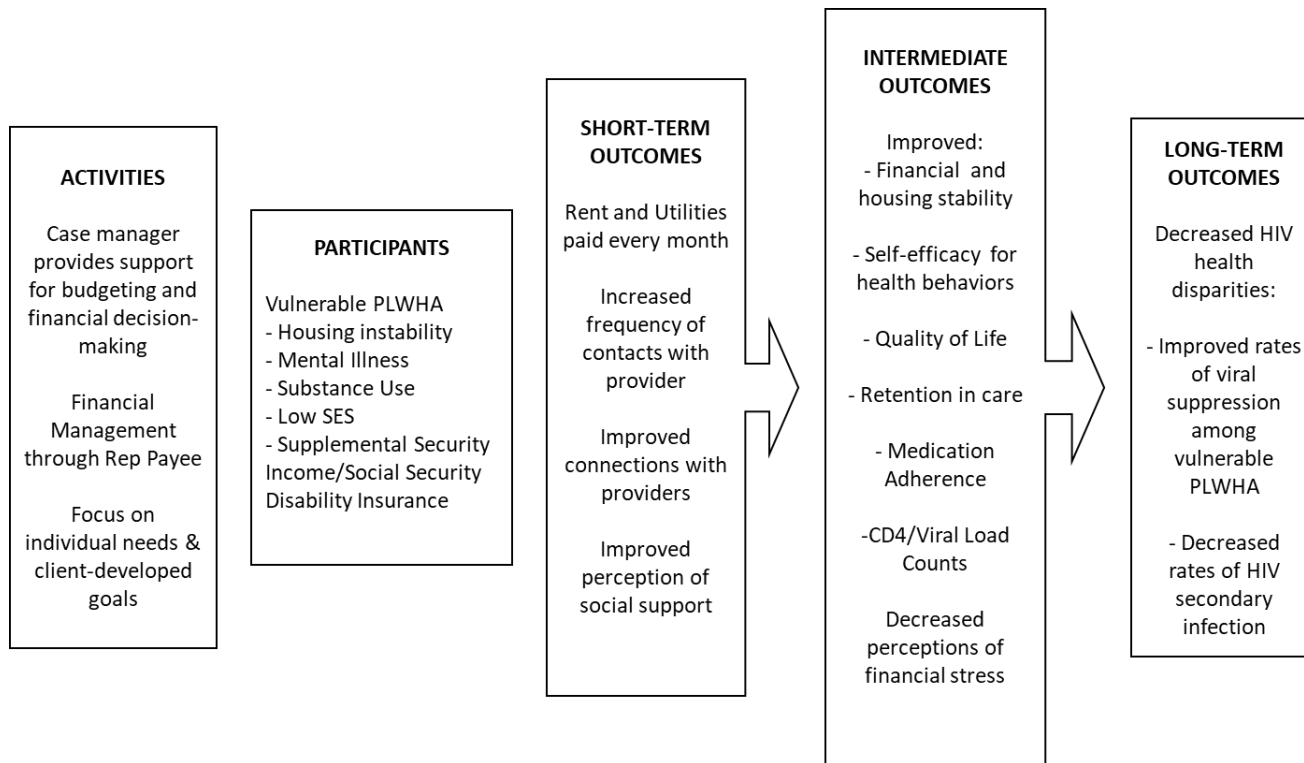


Figure 2. CCRP Theorized Mechanisms of Change



STUDY PROTOCOL

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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 160 PLWHA and cohort study of 50 PLWHA (choice arm).

Aim 1: Conduct a randomized controlled trial (RCT) and cohort study (choice arm) 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. Given this intervention may have value for all study participants, we have measures in place to provide CCRP to control arm participants once their study periods have concluded.

In addition, in the initial years of this study we observed that the RCT design created a barrier for some eligible clients, specifically those who experience significant health and practical challenges and required a representative payee in order to stabilize their housing and health. Study recruiters and the Data and Safety Monitoring Board agreed the possibility of randomizing these individuals to the control created an ethical risk. For this reason, choice arms have been added to the study. Participants (n=25) who demonstrate significant need or who are mandated to receive representative payee services by Social Security will be able to enter the choice intervention arm. To determine if immediate assignment to rep payee via the choice intervention arm is warranted, the following questions will be used to guide discussions with clients and their providers:

- Is there risk of housing loss, as evidenced by multiple evictions, eviction notices, and/or utility shut-offs in the past year?
- Is there risk of money mismanagement because the client is being persuaded to use money in ways they don't want to?
- Would it be unethical to wait to provide Rep Payee services? (Given all participants can get Payee within 12 months.)

Additionally, 25 clients who meet study inclusion criteria will be recruited to the choice control arm. These clients will receive care as usual.

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 160 individuals to intervention or control arms and recruit 50 non-randomized individuals the choice 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. To assess poor adherence, providers will use the CASE Adherence Index (poor adherence is indicated by a CASE Index score of ≤ 10) or 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, The Open Door, and Birmingham AIDS Outreach (BAO) will serve as the intervention sites 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.

The Open Door, Inc. is a grassroots, 501(c)3 non-profit organization located in Pittsburgh city limits. The program has been serving chronically homeless PLWHA since 2006 and is the organization that developed the CCRP intervention. The Open Door (TOD) has served hundreds of marginalized individuals in the past decade, and provides representative payee services to nearly 100 people at any point in time. TOD works to both **solve** the homeless problem for those already on the streets with its supportive homes and **prevent** others from becoming homeless with representative payee services.

Birmingham AIDS Outreach is a 501(c)3 non-profit organization located in Birmingham, Alabama. The organization works in collaboration with the University of Alabama 1917 clinic. They provide free services to HIV positive individuals as well as free HIV testing and prevention services in the greater Birmingham and surrounding areas. The organization provides case management, counseling, and legal services. The mission of the organization is to provide financial, emotional, and home health support to individuals with HIV and AIDS and to provide educational information to the community with the goal of reducing the spread of AIDS. Birmingham AIDS Outreach will work in collaboration with the 1917 Clinic at the University of Alabama for retrieval of the clinical data of enrolled participants.

Staff from the study sites 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. The study sites 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 and Birmingham AIDS Outreach's electronic health record (appointment adherence, exposure to services, and retention in care.) Birmingham AIDS Outreach will work in collaboration with the 1917 clinic at the University of Alabama to retrieve the clinical data of enrolled participants. In Pittsburgh, client CD4, viral load, and appointment adherence data will be abstracted through TOD's electronic database. 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 study sites will be able to link participant IDs with the data collected, only will only have access to their own clients' data; i.e., participant data will not be shared across study sites.

In addition, qualitative interviews will be collected with a subset of participants, eligible individuals who did not want to participate in the study and with providers from the study sites. Given that clients served by other agencies will also be recruited to the study, providers from external organizations will also be recruited to qualitative interviews to assess their interpretation of their clients' experiences with the intervention. Semi-structured interviews with 40 eligible individuals (study participants and non-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. Qualitative interviews with eligible clients who did not want to participate in the study will assist with eliciting issues they had with the study or Representative Payee service. This could assist with identifying procedures or processes to implement to assist with participant recruitment and possibly streamlining the intervention. 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 study sites' research teams will inform eligible clients including study participants and non-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 sites 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 sites. In addition, staff from Action Wellness and TOD will provide information about the study to other local providers (in Philadelphia and in Pittsburgh) to enable them to refer people not currently served at TOD or Action Wellness to enroll in the study if they meet inclusion criteria. Flyers announcing the opportunity to participate in the study will also be posted in the waiting and patient rooms at Action Wellness, TOD and BAO, as well as with external providers wishing to promote the study, so that individuals may self-refer. In addition, the study team will utilize snowball sampling in active study sites to assist with participant recruitment.

Once individuals are referred to the study sites, the research coordinators and case managers will screen clients for participation per the study inclusion criteria. The research coordinators or 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, 4, 6, 7, 8, 9, and 10 for randomized participants, and 1, 6, and 9 for control arm clients.

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.

Another risk could be the loss of privacy of enrolled clients who were referred to the study due to the provision of a referral incentive to the referee. This could lead to their identification as a study participant and their HIV status. To minimize this risk, participants receiving the referral incentive would not be informed of the identity of the enrolled patient. In addition, referred clients will be informed of the referral incentive to be given to their referee.

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, TOD, and Birmingham AIDS Outreach are bonded as organizational representative payees 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, TOD, and Birmingham AIDS Outreach research teams 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 sites, 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. Clients will be recruited from the CCRP study and from eligible individuals who did not participate in the study. Participants recruited from the CCRP trial will include randomized and choice intervention and control arm participants. Since we are interested in exploring factors related to adherence success, some of the interviews (in both arms) will be conducted with participants who have successfully achieved viral suppression and the other half 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. By interviewing eligible non-participants, interviews will also enable us to understand challenges with the study and/or the intervention (Representative Payee service). Members of the Action Wellness, BAO, and TOD research teams will link clients to the qualitative interviewers by coordinating interview appointments at the study site.

5.2.2 Providers

The University of Pittsburgh investigators will reach out to Action Wellness, TOD, and BAO providers to schedule in-depth qualitative interviews. Given that clients served by other agencies will also be recruited to the study, providers from external organizations and the 1917 clinic at the University of Alabama will also be recruited to qualitative interviews to assess their interpretation of their clients' experiences with the intervention. 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 data or feedback from participating providers (Appendix B.) One-on-one interviews will be held in a private space at Action Wellness, TOD, BAO or external providers' offices, 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. Participants will be recruited during regularly scheduled visits at the intervention sites. In addition, staff from Action Wellness and TOD will provide information about the study to other local providers (in Philadelphia and in Pittsburgh) to enable them to refer people not currently served at TOD or Action Wellness to enroll in the study if they meet inclusion criteria. Flyers announcing the opportunity to participate in the study will also be posted in the waiting and patient rooms at Action Wellness, TOD, and BAO, as well as with external providers wishing to promote the study, so that individuals may self-refer. Also, snowball sampling will be utilized in active study sites as described in section 5.4 below.

In addition, study sites will host several educational workshops to share information about the study. These sessions will take place at the offices of study sites or at community partner sites, such as other social service organizations that may refer clients to the study. Workshops may begin before the active study enrollment period and continue periodically throughout the study as needed. Need for additional workshops will be determined by study sites and the research

team in response to client interest in the CCRP study. The workshops will be conducted by staff members from study sites and the focus will primarily be on how CCRP works. In addition, clients 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.
- Rep PayeePersonal 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 at the conclusion of the 12-month active study period (regardless of randomization or choice arm)
 - Choice arms
 - Timeline (when recruitment will begin, survey schedule)
 - Incentives
- Question and Answer Period

Table 1. Enrollment Targets

2020												2021												2022		
Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
26	26	26	28	34	42	42	50	58	66	74	82	90	103	111	119	127	135	142	153	164	175	186	197	203	220	225

In accordance with NIH Recruitment Milestone Report expectations, the enrollment chart includes randomized participants (n=160), non-randomized (choice) participants (n=50), and providers who participate in qualitative interviews (n=15). Recruitment and participant inclusion/exclusion criteria are described in sections 3.1 and 3.2 above. Due to the inability to recruit new clients in Philadelphia, active participant recruitment by Action Wellness was discontinued in September 2019. Alterations to the study process including the inclusion of choice arms, change in incentive structure and the use of snowball sampling will not affect enrolled participants at Action Wellness or clients in Philadelphia.

5.3.1 Screening

Action Wellness and Birmingham AIDS Outreach Research Coordinators and medical case managers will use their EMR system to screen clients for participation. Birmingham AIDS Outreach will work in collaboration with the 1917 clinic at the University of Alabama to identify potential participants. In addition, screening of potential participants through TOD or through external providers in Philadelphia will take place in person. Potential participants, in collaboration with their

external providers, will be asked to provide proof of HIV status, age, social security benefits, income, and viral load. The CASE Adherence index may also be used to assess inclusion criteria related to adherence.

5.3.2 Consent

Signed informed consent will be obtained by the Research Coordinators or case managers at Action Wellness, TOD, and BAO. 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 study sites' research coordinators will track participant retention, which will be reviewed bi-weekly by the PI (Hawk) and co-PIs (Hagan, and Batey.) Though loss to follow-up is a concern, this is lessened by the use of incentives for follow-up assessments in the four 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. As needed, case managers at the intervention sites will meet with participants to address concerns and prevent drop-out.

5.4 Incentives

Randomized participants will receive up to \$240 in incentives, while participants in the choice arms will receive up to \$120, if they complete all self-assessment surveys as follows.

Table 2. Incentives Schedule

Month	Survey	Randomized Participants	Choice Participants
Baseline	Full Survey	\$20	\$20
1	Mini Check-in	\$20	\$20
2		\$20	
3	Short Survey	\$20	\$20
4	Mini Check-in	\$20	
5	Mini Check-in	\$20	
6	Full Survey	\$20	\$20
7	Mini Check-in	\$20	
8	Mini Check-in	\$20	
9	Mini Check-in	\$20	\$20
10	Mini Check-in	\$20	
12	Full Survey	\$20	\$20
Total		\$240	\$120

When possible, assessments will be scheduled in conjunction with regular clinic visits to increase convenience for participants.

In addition, individuals who visit the study site to be screened for study participation will receive \$5 in gift card incentives.

Finally, participants who refer clients to the study can receive up to 5 additional gift cards each in the amount of \$20 when referred individuals are randomized to the study. To facilitate this process while protecting confidentiality, participants will be given referral cards with non-identifiable unique codes to share with people in their social networks

they think may be eligible for and benefit from the study. When new participants are randomized and they present the study team with a referral card, the referring participants will receive a \$20 gift card. Neither referred nor referring participants will be given names of those referring or referred. Additionally, when participants are given referral cards to share with others, the study team will discuss with them the fact that because of the nature of the study, by revealing one's own participation in the study they are also self-disclosing that they meet study inclusion criteria including HIV status.

Participants randomized to the intervention group and in the choice intervention arm will inform the representative payee of their preferred method of receiving expendable funds which includes checks or a visa prepaid card (True Link card). The study will pay for the first procurement (\$5) and monthly charges (\$4) of the True Link card for participants who select this method for disbursement of funds allocated to them. The study will pay for monthly charges for only the 12-month active study period.

Eligible clients including study participants and non-participants who complete interviews will receive \$40 in gift card incentives.

Active client recruitment by Action Wellness has been discontinued (from September 2019) due to lack of eligible clients for the study. The changes made to the incentives and recruitment method (snowball sampling) do not affect Action Wellness. All currently enrolled participants at Action Wellness will continue in the study for the 12-month active study period and abstracted data will also be collected for all the participants for the 24-month period.

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 study sites research coordinators, 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, TOD or BAO.

5.5.2 Study Termination

Participants may be withdrawn from the study if they are also withdrawn from Action Wellness, TOD, or BAO client services. In keeping with Action Wellness, TOD, and BAO policies, 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 in the randomized or choice 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, TOD, or BAO, 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 the intervention sites 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. Study sites will work with participants who are randomized to the intervention group or participate in the choice intervention arm, 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/TOD or BAO 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/TOD/BAO 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 or Birmingham AIDS Outreach.

Participants who are randomized to the control group or participate in the choice 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/TOD/BAO 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/TOD/BAO can be assigned as Rep Payee.

5.5.5 Withdrawal from Rep Payee

Participants can ask to have Action Wellness/TOD/BAO removed as their Rep Payee at any time in the study. If participants no longer want Action Wellness/TOD/BAO to act as their Rep Payee and feel they are able to pay their bills independently, the intervention sites will help participants to have SSA remove Action Wellness/TOD/BAO 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/TOD/BAO 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/TOD/BAO removed as organizational Rep Payee, the study sites will help the participant appeal this decision. This will include linking the participant to free legal services if needed. Action Wellness/TOD/BAO can also help the participant identify a different Rep Payee if desired by the participant.

6.0 Study Procedures

6.1 Randomization Arms

Patients who elect to participate and agree to be randomized 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 study sites' 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 visits in keeping with the study sites 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 Choice Arms

Participants who elect to participate in the choice arm can either be in the intervention or control arm. Once participants submit a consent to participate to a member of study sites' research team, a unique identifier will be generated via REDcaps.

Participants in the choice control arm will continue to attend visits in keeping with the study sites standard of care and normal operating procedures. Participants in the choice intervention arm will receive the same care as the other arms 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 who chose to be in the control group will be offered CCRP services, as they may be interested in the intervention benefits.

6.3 Data Collection

Participants in the four arms will complete the assessment tool at baseline, 3-, 6-, and 12-month time points. 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 client records at Action Wellness/TOD/BAO as shown in Table 3. Birmingham AIDS Outreach will work in collaboration with the 1917 clinic at the University of Alabama to retrieve the clinical data of enrolled participants. 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/TOD/BAO (in collaboration with the 1917 clinic) 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?	Baseline 3-months 6-months

		<p>2. On average, how many days PER WEEK would you say that you missed at least one dose of your HIV medications?</p> <p>3. When was the last time you missed at least one dose of you HIV medications?</p>	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	<p>5 item scale: In the past month, how often did you feel distressed by the following?</p> <ol style="list-style-type: none"> 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/TOD/BAO 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	<p>17-item questionnaire with 4 subscales:</p> <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/TOD/BAO Data Abstraction	Number of supportive services provided by Action Wellness/TOD 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 Representative Payee 	Baseline 6-months 12-months
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/TOD/BAO Data Abstraction	Accounting records and budgets	One-time – not participant specific
Materials and consumables	Action Wellness/TOD/BAO Data Abstraction	Accounting records and budgets	One-time – not participant specific

6.4 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 study sites (Action Wellness, TOD, or BAO.) During the baseline visit, randomized and choice 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.

Case managers at the study sites 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/TOD/BAO will ensure that participants' funds are being used in the participants' best interest.
- Action Wellness/TOD/BAO 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/TOD/BAO will complete all accounting forms as required by SSA.
- Action Wellness/TOD/BAO will report events that may affect participants' benefits, including death or incarceration.
- Action Wellness/TOD/BAO 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) and choice cohort study 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=160) will be randomized to the intervention or to the standard of care. Fifty participants will be enrolled in the choice intervention or choice control arm. The study period is May 2017 –April 2023. 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/TOD/BAO patient records. Birmingham AIDS Outreach will work in collaboration with the 1917 clinic at the University of Alabama to retrieve the clinical data of enrolled participants. Staff at the study sites will recruit, screen, and consent participants, and a full-time Rep Payee employed by Action Wellness/TOD/BAO will provide financial management to participants. Action Wellness/TOD/BAO 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, at TOD in Pittsburgh, PA or at Birmingham AIDS Outreach in Birmingham, AL. Some participants and eligible clients who did not want to participate in the study 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, 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 sites already have 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/TOD/BAO 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/TOD/BAO 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/TOD/BAO removed as the Rep Payee, the study sites will help the participant to appeal this decision or to appoint a different Rep Payee if preferred by the participant.

Another risk could be the loss of privacy of enrolled clients who were referred into the study due to the provision of a referral incentive to the participant that referred them. This could lead to their identification as a study participant and their HIV status. To minimize this risk, we have created a referral card process using non-identifiable numbers so that participants receiving the referral incentive would not be informed of the identity of the newly enrolled (referred) participants. (See section 5.4.)

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 sites, 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

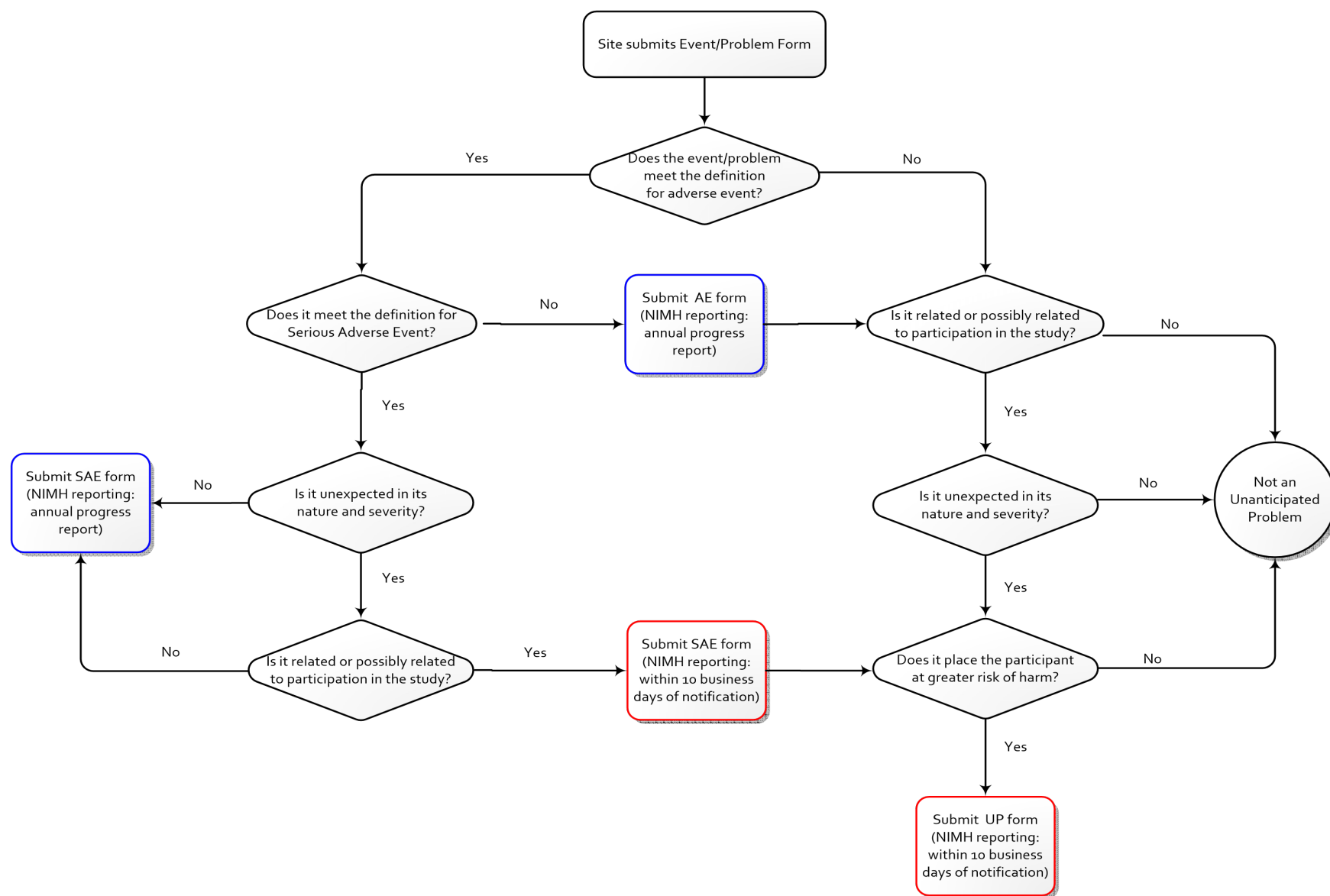
Data that is abstracted from patient records at the study sites will be collected by the study sites and provided to the Coordinating Center via a scheduled transfer using PittBox as a temporary transfer vehicle. Data will be deleted from Pittbox within 24 hours of scheduled transfer then uploaded to 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 eligible clients 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 and Birmingham AIDS Outreach (and the 1917 clinic) 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/TOD/BAO on a quarterly basis, and these values will be provided to the University of Pittsburgh via data extraction from electronic health records. Birmingham AIDS Outreach will work in collaboration with the 1917 clinic at the University of Alabama to retrieve the clinical data of enrolled participants. 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 and choice 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 randomized and choice 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 conduct a propensity analysis to control for confounding variables in estimating our intervention effect. Also, 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 of 0.50 is reasonable for ART therapy in a broad population. Moreover, an effect size of 0.5 is generally considered 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
0.40	200	266
0.45	158	211
0.50	128	171
0.55	106	141

Based on these estimates, we plan to enroll a sample of 160 participants in the randomized study arm. If greater than 80% of participants contribute at least some follow-up data, the trial would have 128 clients with analyzable outcome data. This study would then have 80% power to detect a difference between the intervention and control groups of 0.5 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 0.608. Since 0.50 is considered a medium effect size, the trial is powered to detect medium effect sizes

between the intervention groups for these key outcome measures.

9.3 Semi-Structured Qualitative Interviews

Semi-structured interviews with 40 eligible clients (study participants and non-participants) and 15 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 eligible clients using the theoretical framework described above. Drafts of the interview guides are attached as Appendix C. The interviews with providers and study participants will explore factors perceived 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, interviews with eligible clients who did not want to participate in the study will elicit their perception of the study and the intervention. We will purposively sample study participants 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 sites 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 sites 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, TOD and BAO), 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. TOD will not only recruit participants to the intervention at the Pittsburgh study site, but will also support Action Wellness and Birmingham AIDS Outreach in intervention delivery.

Specifically, TOD will support Action Wellness and Birmingham AIDS Outreach 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 two of the study sites are 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, The Open Door and Birmingham AIDS Outreach 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 study sites research team.

Specifically, we have budgeted funds to cover the costs of the PI (Hawk) to travel to Philadelphia and Alabama to meet with the Co-PIs of the study sites and the research team of these sites 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 and Alabama 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 sites to develop study design, data collection methods, and analysis (Table 4.) In months when investigators do not travel to Philadelphia and Alabama, 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, The Open Door and Birmingham AIDS Outreach 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>

☐ Anonymous data – at no time will any identifiers be collected including IP addresses

Check all identifiers that will be collected below:

(If any identifiers will be collected, a data security review may be required)

<input type="checkbox"/> Name	<input type="checkbox"/> Biometric identifiers, including finger and voice prints
<input type="checkbox"/> Electronic mail address	<input type="checkbox"/> Full face photographic images and any comparable images
<input type="checkbox"/> Social security number	<input type="checkbox"/> Health plan beneficiary numbers
<input type="checkbox"/> Telephone number	<input type="checkbox"/> Account numbers
<input type="checkbox"/> Fax number	<input type="checkbox"/> Certificate/license numbers
<input type="checkbox"/> Internet protocol (IP) address	<input type="checkbox"/> Vehicle identifiers and serial numbers, including license plate numbers
<input type="checkbox"/> Medical record number	
<input type="checkbox"/> Device identifiers/serial numbers	
<input type="checkbox"/> Web Universal Resource Locators (URLs)	

Certain dates, age, zip codes or other geographic subdivision that could be personally identifiable per the standards below.

☐ All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes.

☒ 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

☒ **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. 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, Action Wellness, TOD, or BAO.

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, TOD, or BAO 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 C. Semi-Structured Interview Protocol (Drafts)

Participant Protocol

Domain: History with Provider

1. Tell me about when you first came to Action Wellness/TOD/BAO.
 - 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?

Eligible Non-Participant Protocol

Domain: History with Provider

1. Tell me about when you first came to Action Wellness/BAO/TOD.
 - What services do you get here?
2. What are your relationships with your providers like?
 - Action Wellness/BAO/TOD? What about your medical providers? Other social service agencies?
 - How does AW/BAO/TOD support you in getting medical care? Taking your pills?
 - Overall, how satisfied are you with your care? Medical? Case management?
3. 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?
 - Do you feel like this changed during the last year in the research study? Why or why not?
5. What about taking your meds?
 - Do you feel like this changed during the last year in the research study? Why or why not?
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?
 - What, if anything, about the way you live makes it hard for you to take care of your health?
 - How has your housing situation changed in the past 12 months?
9. Who do you turn to when you are stressed or worried?
 - In what kinds of ways do they help you?
 - How involved in your HIV care are they?
 - How have these relationships changed in the past year?
 - How has your relationship with your providers 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?
 - How does this affect your health?
 - What do you do when you feel upset about finances?
 - Have you had any experiences with payday lending companies? (Philly: OneMain Financial, Advanced Money Loans, ACE Cash Express) If so, tell me about how those experiences affected your finances.

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

- [If yes to predatory lending] How has your situation with predatory loans changed or stayed the same in the past year?

Domain: Satisfaction with Services

12. 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?

- Had you ever heard about representative payee before?
- What are your thoughts about representative payee?

13. Would you ever consider having a Rep Payee?

- What do you think would be good about this service?
- What do you think would be bad about this service?

14. Do you know anyone who has had a Rep Payee?

- Where did they get this service?
- What have they told you about it?

15. What were your thoughts about the study?

- What were your concerns about being a part of the study?
- What factors influenced your decision about not participating in the study? What could have changed this?
- Do you have any recommendations for the researchers with regards to the study or representative payee?
- Do you have any recommendations for the researchers or Action Wellness/TOD/BAO with regards to the recruitment of clients?

Provider Protocol

Domain: History with Provider

1. Tell me what you do in your role as _____.
 - 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 D. University of Pittsburgh IRB Approval Letter

3/3/2020

<https://www.osiris.pitt.edu/osiris/Doc/0/HM8PCAUIB9SKP4MR0N4T7R5PB2/fromString.html>

University of Pittsburgh Institutional Review Board

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

Memorandum

To: Mary Hawk, DrPH, LSW
From: IRB Office
Date: 2/19/2020
IRB#: [MOD17080613-08](#) / PRO17080613
Subject: sIRB: 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 Institutional Review Board reviewed and approved the requested modifications by expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110.

Modification Approval Date: 2/19/2020
Expiration Date: 8/7/2020

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

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

Appendix E. Philadelphia Health Department IRB Approval Letter

OMB No. 0990-0263
Approved for use through 9/30/2021

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, LSW (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. PWAD0003616, the expiration date 12/31/2021 IRB Registration No. IRB00000032
- ☐ This Assurance, on file with (agency/dep) _____, 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 19102	
11. Phone No. (with area code) 215-686-5244	12. Fax No. (with area code)	15. Title Chief Epidemiologist	
13. Email: Raynard.washington@Phila.Gov			
14. Name of Official Raynard Washington, PhD		16. Title	
18. Signature 		17. Date 04/06/18	

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CITY OF PHILADELPHIA



DEPARTMENT OF PUBLIC HEALTH INSTITUTIONAL REVIEW BOARD HEALTH CENTER #5
1900 N 20th Street Philadelphia, PA 19121
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www.phila.gov/health/irb

February 12, 2020

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

Thomas A. Farley, MD, MPH Health Commissioner

Caroline Johnson, MD Chairperson

Jessica M. Robbins, PhD Administrator

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] has approved the revisions for the above subject research proposal submitted on October 20, 2019, with follow up revisions submitted on November 19, 2019, December 9, 2019, January 9, 2020, and January 21, 2020, through expedited review. We note the following revisions:

- Conduct qualitative interviews with eligible clients who did not choose to participate in the study intervention
- New consent form and alterations to protocol to reflect the additional qualitative interviews
- Termination of recruitment of participants in Philadelphia

You may proceed with this project through April 5, 2020, or closure, if sooner. An update report will be required at least one month before the expiration of the approval period. Remember to report changes in investigators, contact information, procedures or consent procedures or forms to the Institutional Review Board before they are implemented. Any intentional or serious protocol violations or serious adverse events must be reported to this office within two working days of discovery. Non-serious adverse events and unintentional protocol deviations should be reported upon your receipt of a DSMB summary report or with your continuing review update report.

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Approval by the IRB does not, in and of itself, constitute approval for the implementation of this research. Other City approvals may be required before study activities are initiated. Research undertaken in conjunction with individuals or entities external to the City will typically require a data license agreement or other contractual arrangement. If any of these approvals require changes to the IRB-approved protocol, recruitment materials, or informed consent/assent document(s), the changes must be submitted to and approved by the IRB prior to beginning the research study. **Principal investigators are responsible for assuring receipt of all required approvals.**

If you have any questions, please contact us at IRB_submissions@phila.gov or 215-685- 0869.

Sincerely,

Digitally signed by Jessica M. Robbins
DN: cn=Jessica M. Robbins, o=Philadelphia Department of Public
Health, ou=Institutional Review Board,
email=jessica.robbsins@phila.gov, c=US
Date: 2020.02.12 10:18:04 -05'00'

Jessica M. Robbins, PhD
Administrator Institutional
Review Board

Jessica M. Robbins

cc: Study #2017-67

C. Johnson, MD (Chairperson)

C. Terrell (PDPH/AACO)

Appendix F. 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/TOD 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: __ __ / __ __ / 2 0 __ __
mm dd yyyy

Date site became aware of event: __ __ / __ __ / 2 0 __ __
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: _____

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