**Project Title:** Influence of Food Insecurity on Adherence

**SRG Action:** Impact/Priority Score: 50 Percentile: 48 

**Human Subjects:** 30-Human subjects involved - Certified, no SRG concerns

**Animal Subjects:** 10-No live vertebrate animals involved for competing appl.

**Gender:** 1A-Both genders, scientifically acceptable

**Minority:** 1A-Minorities and non-minorities, scientifically acceptable

**Children:** 1A-Both Children and Adults, scientifically acceptable

Clinical Research - not NIH-defined Phase III Trial

<table>
<thead>
<tr>
<th>Project Year</th>
<th>Direct Costs Requested</th>
<th>Estimated Total Cost</th>
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ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.
RESUME AND SUMMARY OF DISCUSSION: This application proposes to examine medication adherence, mood, substance abuse and food security in a group of 450 HIV+ individuals. The participants will be asked to respond to daily text messages (nine questions about mood, food security and substance use) and to cooperate with biweekly unannounced pill counts. A second aspect of the proposed study is to evaluate the impact of an incentive payment schedule – biweekly, monthly or bi-monthly. The study is theoretically grounded and the evaluation of factors known to impact medication adherence gives it the potential to have a significant impact. In addition, the research team is strong and very experienced. However, the committee found several aspects of the proposed study to be unclear. In particular, the committee questioned the proposal’s ability to observe mood, food security and substance abuse while coupling it with an intervention that addresses differential incentives for responding to text messages and medication adherence. In addition to this major weakness, there were other minor concerns which further limited the committee’s overall enthusiasm for the application.

DESCRIPTION (provided by applicant): Strict adherence to antiretroviral medications is necessary for people living with HIV/AIDS to achieve sufficient viral suppression to slow HIV disease. Unfortunately, food insecurity is a known barrier to medication adherence. Research shows that as many as half of people living with HIV/AIDS in US cities and surrounding areas experience periodic hunger and that food insecurity is strongly associated with poor treatment adherence. Food insecurity is a marker of poverty and therefore co-occurs with other social problems including substance use and daily stress. Research on food insecurity in relation to health behaviors has not been guided by theoretical models to explain the impact of poverty on health behavior. Determining the mechanisms that account for the links between food insecurity and medication adherence will refine models of medication adherence under adverse conditions and inform programming designed to alleviate poverty-related health disparities. We propose a 12-month prospective cohort study to examine food insecurity in relation to HIV treatment adherence. We will use Conservation of Resources Theory of Stress and Coping as a conceptual framework for the study. We hypothesize that food insecurity will predict non-adherence to treatment over and above other factors associated with poverty, including quantity and frequency of alcohol and other substance use. We will also embed experimental conditions of participant payment disbursement schedules within the cohort to conduct the first experimental study of monetary resources on food consumption, stress, and substance use in relation to medication adherence. We predict that access to monetary resources will be associated with treatment adherence. However, the direction of the effects of monetary resources on adherence will depend on food access and consumption. The study will include an innovative combination of reliable and valid technologies for objectively monitoring HIV treatment adherence, food consumption, mood, and substance use. We will enroll a cohort of 450 men and women who are (a) 18 years of age or older, (b) HIV positive and currently taking antiretroviral medications, and (c) report using alcohol or other drugs in the past month. Participants will be blocked by experiencing food insecurity in the previous month and randomly assigned to receive study participation payments in either (a) biweekly, (b) monthly or (c) bimonthly disbursements using a non-burdensome ATM/debit card payment method. To monitor HIV treatment adherence, we will use biweekly unannounced pill counts. Food security, mood, and substance use will be monitored using daily interactive text message response technology. Multilevel modeling will test Conservation of Resources Theory in relation to food insecurity and medication adherence over one year. Our findings will inform programs and policies to resolve the adverse effects of poverty on health disparities.

PUBLIC HEALTH RELEVANCE: The benefits of HIV treatment are only realized with persistent strict adherence. Food insecurity and alcohol use are known barriers to medication adherence. The mechanisms by which food insecurity impacts adherence are not known. This research will test a conservation of resources theoretical model to explain these important associations.
CRITIQUE 1:

Significance: 4  
Investigator(s): 2  
Innovation: 5  
Approach: 6  
Environment: 2

Overall Impact: This proposal aims to recruit a cohort of 450 HIV infected patients on ART where medication adherence, mood, food security and alcohol use will be monitored at baseline and after 12 months in the office, daily via text response messaging, and via bimonthly unannounced pill counts (CD4 and viral loads will be assessed via chart review). A randomized experimental design is embedded in the prospective cohort in that 1/3 of the patients will receive monthly reimbursements, 1/3 of the patients will receive reimbursements every 2 weeks, and 1/3 of the patients will receive reimbursements every 2 months (all administered via direct deposits into an account accessed by ATM cards; reimbursements are linked to completion of text responses; patients will be knowledgeable of their schedule of disbursements). The proposal is of moderately high impact since the investigator proposes to assess a number of innovative tools, including phone-based unannounced pill counts, daily text response messaging (not for medication reminders, but to assess hunger, mood and drug use) and provision of reimbursements for each of these activities staggered at different time intervals. However, the observation that food insecurity impacts ART adherence and treatment outcomes has been made and, no matter how innovative and intense the tools of observation, this application essentially proposes to observe this phenomenon further (with a degree of monitoring that may alter the natural history). The randomization scheme differs only in how often the same amount of disbursement is dispensed and is designed to assess if adherence changes are temporally associated with disbursements. However, biweekly, monthly or bimonthly disbursements are not being proposed as a long-term intervention to improve adherence in food insecure participants, although the innovation section stresses that the incentives provided for research in this study will be explicitly examined for their influence on behavior. Therefore, this particular design is limited in that it will neither study a sustainable intervention for food insecurity to determine its impact on adherence and outcomes, nor truly observe a cohort of HIV-infected individuals who are food insecure under a simulation of real-life conditions (since the participants will be contacted daily via text messaging to answer 9 questions and reimbursed for answering).

1. Significance:

Strengths

- The case for why food insecurity is important in HIV-infected populations and its impact on medication adherence and treatment outcomes is compelling
- The applicant stresses that this phenomenon has been well studied and interventions such as provision of food in impoverished areas has been shown to impact adherence
- A unique angle to this question is raised in that provision of resources to food insecure patients with alcohol/drug use may inadvertently increase use of latter (along with proposing a theoretical perspective)

Weaknesses

- The proposal does not directly address its stated “long term goal to inform efforts to provide food support in the context of HIV treatment in substance using populations living in poverty”.

The section on intervention planning with focus groups and patient interviews is listed at the end and is not part of the 5 year work plan.

- Recruiting a cohort of HIV-infected patients who claim alcohol/drug use once in the past month does not enrich the sample for those who use substances regularly. Should clarify degree of substance use required in inclusion criteria as studying the impact of monetary resources on food insecurity and substance use is an innovative aspect of the proposal.

2. Investigator(s):
Strengths
- PI is experienced investigator with a number of publications and ongoing/past NIH grants to investigate HIV prevention and adherence interventions

Weaknesses
- PI and co-PI are both off-site (in Connecticut) with proposed research being conducted in Atlanta
- No biostatistician mentioned in key or supported personnel (just $25,000 budgeted in final year for consultant; would be helpful to mention what resources are available to support the complex repeated measures multi-level modeling required for this work)

3. Innovation:
Strengths
- Investigators well versed in use of mobile technology to monitor treatment adherence and food consumption, mood and substance use
- Daily interactive text messaging interesting method to collect self-interview data

Weaknesses
- Applicant has studied monthly cell phone based pill counts as a method to monitor adherence. Studying pill counts every 2 weeks is an extension of this methodology, but not necessarily a strongly innovative aspect of this proposal
- Research incentives should be minimally allocated to encourage participation but are being explicitly examined here as for their impact on behavior. Provision of $2/day ($720/year) plus free cell phone to participate in this research protocol is a strong incentive to stay engaged, but design neither truly interventional nor truly observational

4. Approach:
Strengths
- Studying Atlanta-based cohort important to field given high rates of new HIV infections in the area, as well as high rates of poverty and substance use
- Enrolling equal number of men and women will allow sex differences in food insecurity, mood and substance use to be assessed

Weaknesses
Neither a truly observational design nor an interventional one; will have unclear significance to the field if cannot generalize observations to a typical population of food-insecure HIV-infected patients nor systematically assess a sustainable food insecurity intervention with robust controls

Expensive to recruit a de novo cohort of 450 HIV-infected patients to study intensively for 12 months without an interventional component that can be translated to the real-world; may be more cost-effective to conduct observational research in the context of an ongoing clinic-based or interval cohort

Daily interactive text messaging of responses to 9 questions may lead to rote responses and text fatigue; daily responses may not be necessary to intensively study this population

Provision of $720 a year for participation in this research plus free cell phone with text messaging capability may provide high incentive for retention, but may alter real-world circumstances to the point that observations not generalizable

Provision of $720 a year may have impact on adherence, food insecurity and substance use, but only being studied with a staggered disbursement pattern without a robust control so not an interventional study

Chart abstraction for CD4 and viral loads (and weight) implies level of engagement of care that may not allow generalizability of study findings to those who are not retained in care

Plans to develop an intervention are mentioned at the end of the application with focused interviews of study participants and service providers. Given the proposed budget and expense of recruiting 450 HIV-infected patients for this study, as well as the impressive experience of the investigative team in conducting interventional research, aims 2 and 3 could be addressed more robustly with a design that is truly interventional

5. Environment:

Strengths

- Atlanta-based study important to field given incidence and prevalence of HIV infection, poverty and substance use in the city
- U. of Connecticut provides strong research environment and support

Weaknesses

- None

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

- Investigators do address the fact that level of compensation proposed in this research is high and may pose a burden to participants at the end of the study.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Unacceptable

- Investigators comment in human subjects section that they intend to study the effects of resources on adherence in an experimental manner; the DSMP should reflect the experimental component as well as address the prospective observational design
Inclusion of Women, Minorities and Children:
G1A - Both Genders, Acceptable
M1A - Minority and Non-minority, Acceptable
C1A - Children and Adults, Acceptable

Vertebrate Animals:
Not Applicable (No Vertebrate Animals)

Biohazards:
Acceptable

Resource Sharing Plans:
Acceptable

Budget and Period of Support:
Recommend as Requested

CRITIQUE 2:
Significance: 3
Investigator(s): 2
Innovation: 4
Approach: 5
Environment: 1

Overall Impact: This application proposes to elaborate the impact of food insecurity, mood, and alcohol and drug use on medication non-adherence. Grounded in Conservation of Resources Theory, the project is organized around a blocked randomized experimental study to facilitate a more explicit examination of the impact of study reimbursement as a form of monetary resources. The applicant proposes to collect a comprehensive array of assessment data from 450 HIV positive individuals and to monitor participants’ access to food, mood, substance use, and adherence frequently using sophisticated cell phone data collection procedures over a 12 month period. The overall focus of the project and basic research design are strong and focus on an important set of factors known to influence medication adherence; however, the experimental component of the study needs further development to provide a clearer understanding of how monetary resources influence the dynamics the investigators propose to examine.

1. Significance:

Strengths
- The study proposes an in-depth examination of how food insecurity (and other indicators of poverty), mood, and alcohol and drug use influence medication non-adherence over time.
While prior research has documented that these factors shape medication non-adherence, very little is known about the underlying associations or how they work together or independently to shape medication adherence.

- The research will examine explicitly the impact of monetary study incentives on participants’ health behavior and clinical outcomes overtime.

**Weaknesses**

- While the Conservation of Resources Theory is a potentially valuable framework, the theoretical and operation definition of resources is primarily psychological and deeply subjective. This conceptualization limits the potential significance in that it will not provide a clear understanding or empirical economic evidence regarding the minimum amount of resources needed to improve adherence in different populations.

2. **Investigator(s):**

**Strengths**

- The PI and Co-PI have extensive experience in HIV-related behavioral and clinical research are well qualified to carry out this study. The PI also has published on the importance of food insecurity as a predictor of HIV-related clinical outcomes.

**Weaknesses**

- Neither the PI or Co-PI appear to have training or significant experience in behavioral economics. This specific type of expertise would strengthen the research team.

3. **Innovation:**

**Strengths**

- The study is innovative in its overall aim to apply and develop a theoretical model to understand how food insecurity, mood, substance use influence and medication non-adherence.
- The proposed experiment regarding the impact of study incentive payments to observe the effects of incoming resources on health-related outcomes is potentially innovative.

**Weaknesses**

- The innovation associated with the experimental component is limited because of its restriction to the timing of study incentives (e.g., biweekly, monthly, bimonthly).

4. **Approach:**

**Strengths**

- The Conservation of Resources Theory is a major strength of the present application because it provides a clearer framework for understanding the underlying relationships among a set of potentially-related constructs and their individual and joint effects on medication adherence.

**Weaknesses**

- While the guiding theoretical framework may contribute to a better general scientific understanding, it is rooted in stress and coping research and conceptualizes access to monetary resources primarily as a subjective stressor. Behavioral economics theory and research, however, suggests that individuals’ perceptions of money are a more multi-faceted
and contingent upon both subjective attitudes and objective circumstances (e.g., a person’s income level can shape their perception of the value of monetary incentives).

- The reliance on measuring available resources in terms of the respondents’ subjective assessment of losses and gains will impose significant limitations on the researchers’ ability to “inform programs and policies to resolve the adverse effects of poverty on health disparities.” While the research design may be able to suggest whether more frequent or less frequent monetary payments are significant, it is not likely to provide clear guidance regarding the appropriate amounts for particular economic circumstances.

5. Environment:
Strengths
- The environment at the University of Connecticut and the Atlanta-based, Southeast HIV/AIDS Research and Evaluation (SHARE) Project are very strong and well-suited for carrying out the aims of the proposed project.

Weaknesses
- The PI and the Co-PI are physically located in Connecticut while the study will be carried out in Atlanta. While this could pose project management challenges, the applicants have included a detailed plan and travel funds to ensure that they will be able to execute the project efficiently. They also have had prior experience in managing research projects being carried out in other geographic locations.

Protections for Human Subjects:
Acceptable Risks and/or Adequate Protections
- The overall plan for the protection of human subjects is both adequate and acceptable. The applicant has carefully detailed the potential risks and benefits associated with the study and will inform the subjects carefully. The applicant also has provided a clear rationale for distributing the study incentives differently and ensured that all subjects will benefit from this research equally.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):
Acceptable
- While the overall study will not test an intervention, the applicant proposes an acceptable DSMP because of the vulnerability of the proposed study sample. The DSMP will rely on the IRB at the University of Connecticut to assist in monitoring adverse events.

Inclusion of Women, Minorities and Children:
G1A - Both Genders, Acceptable
M1A - Minority and Non-minority, Acceptable
C1A - Children and Adults, Acceptable
- The targeted sample of 450 subjects will include both genders (50% females and 50% males) as well as both minority and non-minority populations. The majority of the respondents are expected to be African America which reflects the broader epidemiology of HIV in the Atlanta metropolitan area.
Vertebrate Animals:
Not Applicable (No Vertebrate Animals)

Biohazards:
Not Applicable (No Biohazards)

Resource Sharing Plans:
Acceptable

Budget and Period of Support:
Recommend as Requested

CRITIQUE 3:

Significance: 4
Investigator(s): 2
Innovation: 4
Approach: 5
Environment: 2

Overall Impact: This research has the potential to inform a variety of lines of research describing the relationships among medication adherence and food insecurity, as well as the development of interventions, programs and services to address the intersection of these issues. The project has the potential to extend beyond HIV/AIDS to impact work on medication management in other chronic diseases under either food insecurity or other resource constraints. Issues that weaken the overall impact of the project include the need to address issues associated with the built environment relative to food insecurity, recruitment and retention issues related to those outside the city and their access to project facilities and incentives, and clarification of model components, particularly those associated with gained resources.

1. Significance:

Strengths
- Additional research on food security and its relationship to medication adherence among HIV positive individuals is warranted. This is particularly important given the current and projected world economic climate.
- Intervention research as well as clinical practice and social service program development would benefit from clarification on the relationship between food insecurity and HIV treatment.

Weaknesses
- Real world applications and stronger connections to intervention planning need to be clearly addressed.
2. Investigator(s):

Strengths
- The PI has extensive experience in HIV/AIDS research and in working with underserved populations, including work that provides the foundation for the monitoring approach.
- The PI has led members of the team and the SHARE Project for well over a decade with impressive productivity.

Weaknesses
- The team might benefit from a food security expert, especially in terms of the impact of the built environment and access issues for poor populations.

3. Innovation:

Strengths
- The project extends the use of Conservation of Resources Theory of Stress and Coping into the arena of food insecurity and health behavior and health outcomes. This provides the potential to not only expand or refine the theory, but also advance the study of food insecurity and its study in new ways.
- The project also extends the use of mobile interactive text methods previously used by the PI to monitor alcohol consumption. The new use encompasses food access/consumption, medication adherence, and mood in addition to substance use.

Weaknesses
- The innovations in terms of ATM for payments may create barriers for some participants, particularly those outside of Atlanta.

4. Approach:

Strengths
- The project proposes to recruit a diverse sample of HIV positive men and women over 18 years of age, and using an array of computerized, mobile interactive, and PACA data to investigate the relationships among medication adherence, food security, mood, and substance use.
- The project is guided through new application and adaptation of the Conservation of Resources Theory of Stress and Coping.
- The project has anticipated and addressed a variety of potential barriers (e.g., changes in medication regimens, concerns regarding participant payments, issues related to drop outs).

Weaknesses
- The Theoretical Framework as described does not seem to align with the Figure. The disconnect lies in the “gained resources” and their relationship to coping and stress management versus only medication adherence.
- The impact of the environment (easy access to food stores and storage of non perishable items) in the model and the assessments is unclear.
- The intervention planning section describes an “in-depth exit interviews with all study participants” that does not seem to be described in the remainder of the application.
• The project costs for the establishment of the ATM bank accounts and accessibility for participants, particularly those outside of Atlanta, is unclear.

• Additional information is needed regarding the utility of PACA in relationship to the project, particularly in terms of timing of healthcare provider visits relative to project data collection (baseline and 12 months).

• No discussion of participant transportation barriers/costs for office visits, particularly for recruitment outside of Atlanta. It would seem that distance from the project office might impact involvement and the premise of additional resources for some and not other participants.

5. Environment:
Strengths
• Project SHARE established presence in the community and with community collaborators is a strength.
• The PI and Project SHARE have an established track record of HIV/AIDS research in the community.

Weaknesses
• Distance of the facility from suburban or rural participants for baseline and 12 month assessments may impact or bias recruitment. This could be a concern given the project’s need to recruit outside Atlanta to secure sufficient numbers of women.

Protections for Human Subjects:
Acceptable Risks and/or Adequate Protections
Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):
  Acceptable

Inclusion of Women, Minorities and Children:
G1A - Both Genders, Acceptable
M1A - Minority and Non-minority, Acceptable
C1A - Children and Adults, Acceptable

Vertebrate Animals:
Not Applicable (No Vertebrate Animals)

Biohazards:
Not Applicable (No Biohazards)

Budget and Period of Support:
Recommend as Requested
THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE

INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE

INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE

INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

# Ad hoc or special section application percentiled against "Total CSR" base.


The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.
MEETING ROSTER

The roster for this review meeting is displayed as an aggregated roster that includes reviewers from multiple Center for Scientific Review Special Emphasis Panels of the AARR IRG for the 2012/01 council round. This roster is available at: