UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
Clinical Research Protocol
SILICON VALLEY GUARANTEED INCOME PILOT PROTOCOL

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PROTOCOL AGREEMENT

I have read the protocol specified below. In my formal capacity as Investigator, my duties include ensuring the safety of the study participants enrolled under my supervision, as outlined in the protocol. It is understood that all information pertaining to the study will be held strictly confidential and that this confidentiality requirement applies to all study staff at this site. Furthermore, on behalf of the study staff and myself, I agree to maintain the procedures required to carry out the study in accordance with accepted GCP principles and to abide by the terms of this protocol.

Protocol Number: v1.4

Protocol Title: SILICON VALLEY GUARANTEED INCOME PILOT PROTOCOL

Protocol Date: 10/28/22

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Investigator Signature *Date*

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Print Name and Title

Site # _____

Site Name _____

Address _____

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LIST OF ABBREVIATIONS

AE	adverse event
BIPOC	Black, Indigenous and People of Color
CFR	Code of Federal Regulations
CRF	case report form
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
GI	guaranteed income
HIPAA	Health Insurance Portability and Accountability Act of 1996
ICF	informed consent form
ICH	International Conference on Harmonisation
IEC	Independent Ethics Committee
IRB	Institutional Review Board
PI	Principal Investigator
RRH	Rapid Rehousing Assistance
VI-SPDAT	Vulnerability Index – Service Prioritization Decision Assistance Tool

PROTOCOL SYNOPSIS

TITLE	Silicon Valley Guaranteed Income Pilot
SPONSOR	
FUNDING ORGANIZATION	UCSF Benioff Homelessness and Housing Initiative
NUMBER OF SITES	1
RATIONALE	Homelessness is a national public health crisis in the United States. Over 600,000 people experience homelessness on any given night, with Black, Indigenous, and People of Color (BIPOC) disproportionately affected, and with the highest rates of homelessness in regions with high housing costs. Individuals experiencing homelessness have high rates of chronic physical and mental health conditions, are at higher risk for contracting, transmitting, and suffering complications from communicable illnesses, and more frequently need emergency and acute health services. The cumulative consequences of homelessness are massive human suffering and strain on essential public health and medical systems, which spend vast resources on treating the downstream health sequelae of chronic homelessness. Guaranteed income (i.e., unconditional cash transfer) is a promising intervention for reducing poverty and material hardship but there are few U.S.-based studies on guaranteed income overall, and none designed for alleviating homelessness. Thus, our objective is to assess the effect of guaranteed income on housing stability among individuals experiencing homelessness.
STUDY DESIGN	Randomized controlled trial
PRIMARY OBJECTIVE	Assess the effect of guaranteed income on receipt of stable housing
SECONDARY OBJECTIVES	Assess the effect of guaranteed income on the health and well-being of families experiencing homelessness
NUMBER OF PARTICIPANTS	300
PARTICIPANT SELECTION CRITERIA	Inclusion Criteria: Families with children experiencing homelessness in Santa Clara County Exclusion Criteria: Substantial/severe level of problematic substance use; Hazardous/harmful alcohol consumption and/or active and severe alcohol use disorder

TEST PRODUCT, DOSE, AND ROUTE OF ADMINISTRATION	*A total of $24,000 will be disbursed to participants in the intervention group over a period of 24 months.*
CONTROL PRODUCT, DOSE AND ROUTE OF ADMINISTRATION	*Usual care*
DURATION OF PARTICIPANT PARTICIPATION AND DURATION OF STUDY	*Participants will be followed for 36 months after enrollment.* ***Follow-up:*** *36 months (24 concomitant with period over which participants will be receiving guaranteed income, plus an additional 12 months after the end of guaranteed income payments).* *The total duration of the study is expected to be 48 months. 12 months for participant recruitment and 36 months for final participant follow-up.*
CONCOMMITANT INTERVENTIONS	Allowed: Any and all other federal, state, county, and local/community assistance services that are available to participants
EFFICACY EVALUATIONS	
PRIMARY ENDPOINT	Our primary endpoint is number of days experiencing homelessness
SECONDARY ENDPOINTS	• Time spent unsheltered and/or in unstable housing; physical, mental, social, financial well-being; use of health care and public assistance/social services
STATISTICS **Primary Analysis Plan**	We will conduct intention-to-treat analyses to assess our primary endpoint, including difference in numbers of days spent homeless using Poisson regression
Rationale for Number of Participants	Our community partner service organizations have resources to provide guaranteed income assistance to 150 families; we plan for a total of 300 participants to enable enrollment of a control group of equal size.

1 BACKGROUND

Homelessness is a national public health crisis in the United States. Over 600,000 people experience homelessness on any given night, with Black, Indigenous, and People of Color (BIPOC) disproportionately affected, and with the highest rates of homelessness in regions with high housing costs. Individuals experiencing homelessness have high rates of chronic physical and mental health conditions, are at higher risk for contracting, transmitting, and suffering complications from communicable illnesses, and more frequently need emergency and acute health services. The cumulative consequences of homelessness are massive human suffering and strain on essential public health and medical systems, which spend vast resources on treating the downstream health sequelae of chronic homelessness. Guaranteed income (i.e., unconditional cash transfer) is a promising intervention for reducing poverty and material hardship with a robust evidence base from studies conducted in developing countries. However, there are few U.S.-based studies on guaranteed income overall, and none published on the effectiveness of guaranteed income in alleviating homelessness.

1.1 Overview of Studies

Conceptually, guaranteed income is simple: give a meaningful sum of money directly to people so they are empowered to make purchasing and investment decisions for their own well-being. This is in contrast to existing financial assistance programs to alleviate homelessness which demonstrate promising results but have significant limitations as follows: a) consist of brief periods of assistance; b) are restricted to direct housing-related needs such as rental assistance or moving and utility costs; c) lack flexibility and do not account for the complex and potentially idiosyncratic needs of different families; and d) are associated with high per-person administrative costs.

Guaranteed income (i.e., unconditional cash transfer) is a promising intervention for reducing poverty and material hardship with a robust evidence base from studies conducted in low- and middle-income countries demonstrating decreased monetary poverty, decreased food insecurity, increased school attendance, increased savings, increased work participation, improved access to health care services, and improved child health. Despite the international evidence base, there are few published studies based in the U.S. or in other high-income countries on guaranteed income overall and none published on the effectiveness of guaranteed income in alleviating homelessness, though a number of pilot studies in a variety of settings and populations within the U.S. are currently pending. One study based in Vancouver, Canada assessed the impact of a single lump sum payment equivalent to $5,700 USD on time to housing; preliminary findings suggest that this form of cash assistance helped reduce time to stable housing and improved food security. A second study, the Denver Basic Income Project, will assess the impact of varying unconditional cash transfer payment strategies (monthly vs lump sum vs hybrid) on homelessness over a one-year period of payments; the study will start in Spring 2022.

2 STUDY RATIONALE

Although guaranteed income is a promising intervention for reducing poverty and material hardship, there are few U.S.-based studies on guaranteed income overall, and none published on the effectiveness of guaranteed income in alleviating homelessness. This study will be among the first studies of guaranteed income among families experiencing homelessness in the U.S. and will assess the impacts of guaranteed income over a longer duration (two years) than any other study targeted at individuals experiencing homelessness (other known studies have assessed or are planning to assess outcomes only up to one year).

2.1 Risk / Benefit Assessment

The main risks of receiving guaranteed income (GI) are the same as the risks that would be incurred by the general population in daily life who experience any increase in overall household income: 1) increased income tax burden; and 2) the potential loss of existing public benefits and assistance among participants. Our community partners have primary responsibility for administering and implementing the guaranteed income intervention, and have developed a comprehensive approach to mitigating these risks, including a) limiting the total annual amount of GI to $12,000 per year, an amount that is considered a non-taxable gift rather than income by the Internal Revenue Service and therefore would not be subject to income tax; b) negotiating waivers to ensure that GI is exempt from being included in eligibility calculations for Santa Clara County and California state assistance services such that participants will maintain the same eligibility for services they would have in the absence of GI; c) providing individualized benefits counseling during the study enrollment process so that potential participants can make informed decisions about participation prior to enrolling in the study; and d) creating a Hold Harmless fund to reimburse participants for any unanticipated benefits losses. The primary potential benefit of guaranteed income is that it will act to enhance and supplement existing housing and social assistance services and decrease homelessness and improve housing stability, health, and well-being of participants. These potential benefits outweigh the risks to participants.

The main risks of participating in our research evaluation activities are loss of privacy and confidentiality. There is also the risk of disappointment at not being selected for the guaranteed income intervention group. Our research evaluation activities involve secondary analyses of administrative program data, and prospective data collection through administration of surveys and conducting structured and semi-structured interviews. Our research study team will put into place comprehensive measures to protect the privacy of participants and confidentiality of their data, including a) conducting eligibility screening, informed consent, surveys and interviews by trained research staff in-person and/or by telephone in private settings where responses will not be overheard; b) informing and emphasizing that we will not disclose individual and/or identifiable data collected for the study to anyone outside of the immediate research study team including community partners, community service providers, and/or community members; c) ensuring that identifying information about individual participants will never be included in manuscripts or other presentations of data; d) storing all electronic research data on a secure, encrypted database on a UCSF server that is backed up nightly; e) storing all hard

copies of data in locked, secured cabinets behind locked office doors; and f) de-identifying data for analysis by coding data for a unique evaluation identification number for each participant, and storing the document linking participant identifiers to evaluation identification numbers separate from research data and destroying this document at the end of the evaluation. There will no immediate benefit to participants participating in research evaluation activities, though consent and enrollment in the research evaluation will be a prerequisite to being eligible to being randomized to receive the guaranteed income intervention. Individuals who are randomized to the guaranteed income intervention group will benefit from receiving the income payments.

3 STUDY OBJECTIVES

3.1 Primary Objective

The primary objective of this study is to assess the effect of guaranteed income on housing stability.

3.2 Secondary Objectives

The secondary objectives of this study are to assess the effect of guaranteed income on the health and well-being of families with children experiencing homelessness.

4 STUDY DESIGN

4.1 Study Overview

This is a single-site, single-blinded randomized controlled trial. The community partner service organizations, Destination: Home SV and the ¡Sí Se Puede! Collective, have raised funds to provide unconditional cash assistance in the form of guaranteed income (GI) for a period of two years to 150 families with children experiencing homelessness in Santa Clara County and who are eligible for referral to rapid rehousing assistance programs (RRH). The partner service organizations are prioritizing assistance to those awaiting RRH referral given the current extended wait time for RRH services. Because there are far more families who are eligible for GI than there are available resources, 150 eligible families will be randomly selected to receive GI. From the pool of eligible families, we will also randomly select an additional 150 participants as matched controls for the purpose of evaluation.

Thus, we are planning for a total of 300 participants. Participants will be assigned to either the control (usual care) or intervention (guaranteed income) groups in random order. Evaluations will be taken at baseline and every 6 months monthly via in-person and/or telephone assessments.

Screening data will be reviewed to determine participant eligibility. Participants who meet all inclusion criteria and none of the exclusion criteria will be entered into the study.

The following treatment regimens will be used:

- Intervention – guaranteed income, consisting of a total of $24,000 to be disbursed over 24 months. Participants may opt for either monthly ($1,000/month) or hybrid (lump sum of $6,500 the first month, then $500/month x 11 months for a total of $12,000 per

year) disbursement schedules, with the option to switch disbursement schedule after the first 12 months. Participants will also be invited to attend a Public Benefits Information Session to learn about public benefits and social assistance programs available to residents of Santa Clara County. Participation in this Benefits Information Session will be optional and not required for study participation.

- Control – usual care as per the partner service organizations. Participants will be invited to also attend a Public Benefits Information Session to learn about public benefits and social assistance programs available to residents of Santa Clara County. Participation in this Benefits Information Session will be optional and not required for study participation.

Total duration of participant participation will be 36 months from the time of enrollment. Total duration of the study is expected to be 48 months (12 months for recruitment and 36 months for follow-up from the time of last participant enrolled).

5 CRITERIA FOR EVALUATION

5.1 Primary Efficacy Endpoint

Our primary endpoint is number of days experiencing homelessness (with 'homelessness' as defined below in section 6.2) during the study period.

For our primary endpoint, number of days experiencing homelessness, given our sample size of 300 with 150 participants in each arm, we estimate that we will have 80% power at a two-sided significance level of 0.05 to detect a mean reduction of 24.0 days in the intervention group, assuming a mean of 52.3±74.0 days experiencing homelessness from prior studies. Allowing for a 27% dropout rate as estimated from prior studies (for a total of sample size of 220 participants with 110 families in each arm), we will still have 80% power at a two-sided significance level of 0.05 to detect a mean reduction of 28.0 days in the intervention group.

5.2 Secondary Efficacy Endpoints

- Time to stable housing after randomization
- Proportion of families who obtain stable housing during the 24-month intervention period
- Proportion of families who retain stable housing in the 12 months following the end of the 24-month intervention period
- Number of days spent living in a homeless shelter, in a place not typically used for sleeping, such as on the street, in a car, in an abandoned building, or in a bus or train station, or temporarily in an institution
- Number of days spent residing in a hotel or motel as a form of temporary housing
- Number of days spent residing in a space without any legal right to the space (i.e., residing in a space without a lease)
- Number of days spent in a shared living situation intended to be temporary ('doubled up' with a friend or relative due to being unable to find or afford own housing)

- Proportion of people experiencing homelessness for ≥1 night during study period
- Proportion of people living in a homeless shelter, in a place not typically used for sleeping, such as on the street, in a car, in an abandoned building, or in a bus or train station, or temporarily, in an institution for ≥1 night during study period
- Proportion of people living in a hotel or motel as a form of temporary housing for ≥1 night during study period
- Proportion of people residing in a space without any legal right to the space (i.e., residing in a space without a lease) for ≥1 night during study period
- Proportion of people in a shared living situation intended to be temporary ('doubled up' with a friend or relative due to being unable to find or afford own housing) ≥1 night during study period
- Proportion of people with any return to a homeless shelter at any time after enrollment
- Changes in household composition
- Changes in employment status and household income
- Number of moves
- Overcrowding
- Housing condition, quality, and affordability (i.e., housing cost burden) through selected questions adapted from the American Housing Survey and Family Options Study
- Proportion of monthly income spent on housing-related expenses
- Monthly household expenditures and categories of expenditures, assessed through selected questions adapted from the US Bureau of Labor Statistics Consumer Expenditures Survey
- Physical well-being, as measured through the Short-Form 12 v2
- Psychological well-being, as measured through the Kessler 6
- Financial well-being, through selected questions adapted from the Consumer Financial Protection Bureau Financial Well-Being Scale and the Urban Institute Basic Needs and Well-Being Survey
- Material hardship as measured through selected questions from the Survey of Income and Program Participation and the Urban Institute Basic Needs and Well-Being Survey
- Food insecurity, as measured through the United States Department of Agriculture Household Food Insecurity Survey
- Agency, as measured through the 12-item Adult Hope Scale
- Self-efficacy, as measured through the Generalized Self-Efficacy Scale
- Perceived stress, as measured through the Perceived Stress Scale
- Household environment, as measured through the Chaos, Hubbub, and Order Scale

- Resilience, as measured through the Brief Resilience Scale
- Health conditions and functional status through self-report and administrative data when available
- Social service use through self-report and administrative data when available
- Health service use (including health insurance type) through self-report and administrative data when available
- How cash payments may interfere with vs enhance network strain and support, specifically in terms of the following domains, via semi-structured interviews:
    - Public benefits, services and/or assistance
    - Community and interpersonal relationships
    - Support of friends and family
- The impact of cash payments on time scarcity, self care, and social goods, via semi-structured interviews
- The rationale behind selection of preferred cash payment disbursement schedule, via semi-structured interviews
- The influence and perceived impact of preferred cash payment disbursement schedule on primary and secondary outcomes listed above, via semi-structured interviews
- Household needs not addressed or affected by receipt of cash payments and alternate strategies to meet those needs, via semi-structured interviews
- The long-term positive and adverse effects of cash payments, in the year following completion of the cash payments
- *Incidence of adverse events:* loss or reduction in public benefits, services and/or assistance directly resulting from receipt of cash payments

6 PARTICIPANT SELECTION

6.1 Study Population

Participants living in Santa Clara County and experiencing homelessness who meet the inclusion and exclusion criteria will be eligible for participation in this study.

6.2 Inclusion Criteria

1. ≥18 years of age at baseline visit *and* has a child ≤17 years of age living in household.
2. A resident of Santa Clara County.
3. Experiencing homelessness, as defined by:
    a. The Homeless Emergency Assistance and Rapid Transition to Housing Act (HEARTH Act) final rule on the definition of homelessness as published in the Federal Register in 2011; and/or
    b. Living in a public or private space intended for temporary (≤6 month) residence, such as residing in a hotel/motel; residing in a space without a legal right to the

space and therefore being at threat of being asked to leave at any time (i.e., no lease or unleased); and/or being in a shared living situations intended to be temporary (i.e., being 'doubled up' due to lack of available and/or affordable housing).

4. Vulnerability-Index Service Prioritization Decision Assistance Tool (VI-SPDAT) score within the eligibility range for referral to rapid rehousing assistance programs in Santa Clara County (score of 4-8 for households), when available
5. Written informed consent (and assent when applicable) obtained from participant or participant's legal representative and ability for participant to comply with the requirements of the study.

6.3 Exclusion Criteria

1. *Substantial to severe level of problematic substance use* as defined by the validated Drug Abuse Screening Test (DAST-10) (score of 6-8 or 9-10, respectively).
2. *Hazardous or harmful alcohol consumption, or active and severe alcohol use disorder,* as defined by the validated Alcohol Use Disorders Identification Test (AUDIT) (score of 8-14 and ≥15, respectively).

7 CONCURRENT INTERVENTIONS

All participants will maintain eligibility for all other available housing, social, and economic assistance programs. Participants will not be excluded from receipt of any other housing assistance (nor any other assistance programs) should any be available to them during the study period.

8 STUDY INTERVENTIONS

8.1 Method of Assigning Participants to Treatment Groups

Up to 300 eligible participants will be randomly assigned to the guaranteed income group (intervention) or usual care (control group) using a computer-generated randomization scheme developed by the study team. Eligible participants will be referred by the community partners (DHSV and SSPC) to the study team for consent and enrollment into the study prior to randomization. Once participants are enrolled, they will undergo a baseline assessment before being randomly assigned to either the intervention or control group. Randomization will be stratified by referring community partner (DHSV vs SSPC). Group assignments will be known to our community partners at Sacred Heart Community Service, a neutral third community-based organization contracted by DHSV and SSPC to administer and provide support for the guaranteed income intervention; however, the core study team (investigators and core research staff at UCSF) will be blinded to group assignments.

8.2 Blinding

Due to the objectives of the study, the identity of intervention and control groups will not be known to investigators or core research staff (i.e., the UCSF study team). Due to the nature of the intervention, participants themselves will not be blinded to whether they are

assigned to the intervention arm. Community partners at Sacred Heart Community Service, who are administering the guaranteed income intervention, will also not be blinded to participants' group assignments. The following study procedures will be in place to ensure single-blinded administration of the study intervention:

Randomization will take place using a computer-generated randomization scheme integrated into the REDCap randomization module, after participants are consented and enrolled into the study. The REDCap randomization module allows specification of which study team members are blinded vs unblinded to group assignments. Because our community partners at Sacred Heart Community Service are administering the guaranteed income intervention, they will be unblinded to group assignments out of necessity, and will receive the information on individuals' group assignments via a UCSF data liaison working with the UCSF study team. The remainder of the core UCSF study team, including the PI and all key personnel (other than the biostatistician, the aforementioned data liaison, and a participant notification liaison) will be unaware and blinded to participant group assignments during the conduct of the study. The study blind will be broken on completion of the study and after the study database has been locked.

9 STUDY PROCEDURES AND GUIDELINES

A Schedule of Events representing the data collection procedures to be performed for the duration of the study is diagrammed in Appendix 1.

Prior to conducting any study-related activities, we will obtain written informed consent and the Health Insurance Portability and Accountability Act (HIPAA) authorization must be signed and dated by the participant or participant's legal representative. Participants will be eligible to participate in even if they decline HIPAA authorization and release of health-related data from health care providers (Santa Clara Valley Medical Hospital & Clinics). This HIPAA authorization has also been reviewed and approved by Santa Clara County Counsel for authorization of release of public benefits program-related data (i.e., social services-related data) from Santa Clara County Public Health and Santa Clara County Social Services Agency as detailed in section 14.1).

9.1 Clinical Assessments

9.1.1 Concomitant Interventions

All concomitant interventions in terms of receipt of assistance from other housing, social, and economic assistance programs will be documented at Baseline/Screening and 6-month follow-up surveys and early termination when possible. The type, frequency, and amount of assistance services will be captured. These data on concomitant interventions will be supplemented with administrative data from relevant Santa Clara County agencies and community organizations if available.

9.1.2 Demographics

Demographic information (date of birth, sex/gender, race/ethnicity, education) will be recorded at Baseline.

9.1.3 Medical History

Relevant medical history, including history of current disease, other pertinent chronic illness history, and information regarding underlying diseases will be recorded at Baseline.

9.1.4 Adverse Events

Information regarding occurrence of adverse events will be captured throughout the study. Duration (start and stop dates and times), severity/grade, outcome, treatment and relation to the intervention will be recorded.

10 EVALUATIONS BY VISIT

10.1 Visit/Assessment 1: Baseline Survey Assessment (Month 0)

1. Review the study with the participant (participant's legal representative) and obtain written informed consent and HIPAA authorization and assent, if appropriate.
2. Assign the participant a unique screening number.
3. Record demographic data.
4. Record household composition data (number of household members and children).
5. Administer and record current housing situation and history of homelessness instruments, adapted from the Family Options Study and the California Statewide Survey on Homelessness.
6. Administer and record income and employment survey, adapted from the California Statewide Survey on Homelessness.
7. Record concomitant interventions in terms of receipt of assistance from other housing, social, and economic assistance programs.
8. Administer and record monthly expenditure amounts and categories, adapted from the Survey of Income and Participation.
9. Administer and record Financial Well-Being Scale, adapted from the Consumer Financial Protection Bureau (financial well-being).
10. Administer and record Material Hardship Survey, adapted from the Urban Institute Well-Being and Basic Needs and the Survey of Income and Program Participation (material hardship)
11. Administer and record the USDA Brief Food Security Survey (food security)
12. Administer and record healthcare utilization survey, adapted from the California Statewide Survey on Homelessness
13. Administer and record health conditions and functional status survey, adapted from the California Statewide Survey on Homelessness
14. Administer and record Short-Form 12 v2 (physical health)
15. Administer and record Kessler 6 (psychological health)
16. Administer and record the Generalized Self-Efficacy Scale (self-efficacy)
17. Administer and record the Brief Resilience Scale (resilience)
18. Administer and record the Perceived Stress Scale (perceived stress)

19. Administer and record the Confusion, Hubbub and Order Scale (household chaos)
20. Administer and record the Future Scale (aka the Adult Hope Scale) (agency)
21. Schedule participant for Visit 2 in 180-240 days
22. Randomize participant to study group
23. Connect participant with community partner organization (Sacred Heart Community Service) for further social service assessment and assistance (both control and intervention groups) and orientation/navigation for initiation of guaranteed income payments (intervention group)

10.2 Visit/Assessment 2: 6-Month Survey Assessment (Month 6)

1. Record any Adverse Experiences
2. Concomitant interventions review
3. Record changes in household composition
4. Administer and record current housing situation and history of homelessness instruments, adapted from the Family Options Study and the California Statewide Survey on Homelessness.
5. Administer and record income and employment survey, adapted from the California Statewide Survey on Homelessness.
6. Record concomitant interventions in terms of receipt of assistance from other housing, social, and economic assistance programs.
7. Administer and record monthly expenditure amounts and categories, adapted from the Survey of Income and Participation.
8. Administer and record Financial Well-Being Scale, adapted from the Consumer Financial Protection Bureau (financial well-being).
9. Administer and record Material Hardship Survey, adapted from the Urban Institute Well-Being and Basic Needs and the Survey of Income and Program Participation (material hardship)
10. Administer and record the USDA Brief Food Security Survey (food security)
11. Administer and record healthcare utilization survey, adapted from the California Statewide Survey on Homelessness
12. Administer and record health conditions and functional status survey, adapted from the California Statewide Survey on Homelessness
13. Administer and record Short-Form 12 v2 (physical health)
14. Administer and record Kessler 6 (psychological health)
15. Administer and record the Generalized Self-Efficacy Scale (self-efficacy)
16. Administer and record the Brief Resilience Scale (resilience)
17. Administer and record the Perceived Stress Scale (perceived stress)
18. Administer and record the Confusion, Hubbub and Order Scale (household chaos)
19. Administer and record the Future Scale (aka the Adult Hope Scale) (agency)

10.3 Visit/Assessment 3: 12-Month Survey Assessment (Month 12)

1. Record any Adverse Experiences
2. Concomitant interventions review
3. Record household composition data (number of household members and children).
4. Administer and record current housing situation and history of homelessness instruments, adapted from the Family Options Study and the California Statewide Survey on Homelessness.
5. Administer and record income and employment survey, adapted from the California Statewide Survey on Homelessness.
6. Record concomitant interventions in terms of receipt of assistance from other housing, social, and economic assistance programs.
7. Administer and record monthly expenditure amounts and categories, adapted from the Survey of Income and Participation.
8. Administer and record Financial Well-Being Scale, adapted from the Consumer Financial Protection Bureau (financial well-being).
9. Administer and record Material Hardship Survey, adapted from the Urban Institute Well-Being and Basic Needs and the Survey of Income and Program Participation (material hardship)
10. Administer and record the USDA Brief Food Security Survey (food security)
11. Administer and record healthcare utilization survey, adapted from the California Statewide Survey on Homelessness
12. Administer and record health conditions and functional status survey, adapted from the California Statewide Survey on Homelessness
13. Administer and record Short-Form 12 v2 (physical health)
14. Administer and record Kessler 6 (psychological health)
15. Administer and record the Generalized Self-Efficacy Scale (self-efficacy)
16. Administer and record the Brief Resilience Scale (resilience)
17. Administer and record the Perceived Stress Scale (perceived stress)
18. Administer and record the Confusion, Hubbub and Order Scale (household chaos)
19. Administer and record the Future Scale (aka the Adult Hope Scale) (agency)

10.4 Visit/Assessment 4: 18-Month Survey Assessment (Month 18)

1. Record any Adverse Experiences
2. Concomitant interventions review
3. Record household composition data (number of household members and children).
4. Administer and record current housing situation and history of homelessness instruments, adapted from the Family Options Study and the California Statewide Survey on Homelessness.
5. Administer and record income and employment survey, adapted from the California Statewide Survey on Homelessness.

6. Record concomitant interventions in terms of receipt of assistance from other housing, social, and economic assistance programs.
7. Administer and record monthly expenditure amounts and categories, adapted from the Survey of Income and Participation.
8. Administer and record Financial Well-Being Scale, adapted from the Consumer Financial Protection Bureau (financial well-being).
9. Administer and record Material Hardship Survey, adapted from the Urban Institute Well-Being and Basic Needs and the Survey of Income and Program Participation (material hardship)
10. Administer and record the USDA Brief Food Security Survey (food security)
11. Administer and record healthcare utilization survey, adapted from the California Statewide Survey on Homelessness
12. Administer and record health conditions and functional status survey, adapted from the California Statewide Survey on Homelessness
13. Administer and record Short-Form 12 v2 (physical health)
14. Administer and record Kessler 6 (psychological health)
15. Administer and record the Generalized Self-Efficacy Scale (self-efficacy)
16. Administer and record the Brief Resilience Scale (resilience)
17. Administer and record the Perceived Stress Scale (perceived stress)
18. Administer and record the Confusion, Hubbub and Order Scale (household chaos)
19. Administer and record the Future Scale (aka the Adult Hope Scale) (agency)

10.5 Visit/Assessment 5: 24-Month Assessment (Month 24)

1. Record any Adverse Experiences
2. Concomitant interventions review
3. Record household composition data (number of household members and children).
4. Administer and record current housing situation and history of homelessness instruments, adapted from the Family Options Study and the California Statewide Survey on Homelessness.
5. Administer and record income and employment survey, adapted from the California Statewide Survey on Homelessness.
6. Record concomitant interventions in terms of receipt of assistance from other housing, social, and economic assistance programs.
7. Administer and record monthly expenditure amounts and categories, adapted from the Survey of Income and Participation.
8. Administer and record Financial Well-Being Scale, adapted from the Consumer Financial Protection Bureau (financial well-being).
9. Administer and record Material Hardship Survey, adapted from the Urban Institute Well-Being and Basic Needs and the Survey of Income and Program Participation (material hardship)

10. Administer and record the USDA Brief Food Security Survey (food security)
11. Administer and record healthcare utilization survey, adapted from the California Statewide Survey on Homelessness
12. Administer and record health conditions and functional status survey, adapted from the California Statewide Survey on Homelessness
13. Administer and record Short-Form 12 v2 (physical health)
14. Administer and record Kessler 6 (psychological health)
15. Administer and record the Generalized Self-Efficacy Scale (self-efficacy)
16. Administer and record the Brief Resilience Scale (resilience)
17. Administer and record the Perceived Stress Scale (perceived stress)
18. Administer and record the Confusion, Hubbub and Order Scale (household chaos)
19. Administer and record the Future Scale (aka the Adult Hope Scale) (agency)

10.6 Visit/Assessment 6: 27-Month Assessment (Month 27)

1. Record any Adverse Experiences
2. Concomitant interventions review
3. Record household composition data (number of household members and children).
4. Administer and record current housing situation and history of homelessness instruments, adapted from the Family Options Study and the California Statewide Survey on Homelessness.
5. Administer and record income and employment survey, adapted from the California Statewide Survey on Homelessness.
6. Record concomitant interventions in terms of receipt of assistance from other housing, social, and economic assistance programs.
7. Administer and record monthly expenditure amounts and categories, adapted from the Survey of Income and Participation.
8. Administer and record Financial Well-Being Scale, adapted from the Consumer Financial Protection Bureau (financial well-being).
9. Administer and record Material Hardship Survey, adapted from the Urban Institute Well-Being and Basic Needs and the Survey of Income and Program Participation (material hardship)
10. Administer and record the USDA Brief Food Security Survey (food security)
11. Administer and record healthcare utilization survey, adapted from the California Statewide Survey on Homelessness
12. Administer and record health conditions and functional status survey, adapted from the California Statewide Survey on Homelessness
13. Administer and record Short-Form 12 v2 (physical health)
14. Administer and record Kessler 6 (psychological health)
15. Administer and record the Generalized Self-Efficacy Scale (self-efficacy)

16. Administer and record the Brief Resilience Scale (resilience)
17. Administer and record the Perceived Stress Scale (perceived stress)
18. Administer and record the Confusion, Hubbub and Order Scale (household chaos)
19. Administer and record the Future Scale (aka the Adult Hope Scale) (agency)

10.7 Visit/Assessment 7: 30-Month Assessment (Month 30)

1. Record any Adverse Experiences
2. Concomitant interventions review
3. Record household composition data (number of household members and children).
4. Administer and record current housing situation and history of homelessness instruments, adapted from the Family Options Study and the California Statewide Survey on Homelessness.
5. Administer and record income and employment survey, adapted from the California Statewide Survey on Homelessness.
6. Record concomitant interventions in terms of receipt of assistance from other housing, social, and economic assistance programs.
7. Administer and record monthly expenditure amounts and categories, adapted from the Survey of Income and Participation.
8. Administer and record Financial Well-Being Scale, adapted from the Consumer Financial Protection Bureau (financial well-being).
9. Administer and record Material Hardship Survey, adapted from the Urban Institute Well-Being and Basic Needs and the Survey of Income and Program Participation (material hardship)
10. Administer and record the USDA Brief Food Security Survey (food security)
11. Administer and record healthcare utilization survey, adapted from the California Statewide Survey on Homelessness
12. Administer and record health conditions and functional status survey, adapted from the California Statewide Survey on Homelessness
13. Administer and record Short-Form 12 v2 (physical health)
14. Administer and record Kessler 6 (psychological health)
15. Administer and record the Generalized Self-Efficacy Scale (self-efficacy)
16. Administer and record the Brief Resilience Scale (resilience)
17. Administer and record the Perceived Stress Scale (perceived stress)
18. Administer and record the Confusion, Hubbub and Order Scale (household chaos)
19. Administer and record the Future Scale (aka the Adult Hope Scale) (agency)

10.8 Visit/Assessment 8: 36-Month Assessment (Month 36)

1. Record any Adverse Experiences

2. Concomitant interventions review
3. Record household composition data (number of household members and children).
4. Administer and record current housing situation and history of homelessness instruments, adapted from the Family Options Study and the California Statewide Survey on Homelessness.
5. Administer and record income and employment survey, adapted from the California Statewide Survey on Homelessness.
6. Record concomitant interventions in terms of receipt of assistance from other housing, social, and economic assistance programs.
7. Administer and record monthly expenditure amounts and categories, adapted from the Survey of Income and Participation.
8. Administer and record Financial Well-Being Scale, adapted from the Consumer Financial Protection Bureau (financial well-being).
9. Administer and record Material Hardship Survey, adapted from the Urban Institute Well-Being and Basic Needs and the Survey of Income and Program Participation (material hardship)
10. Administer and record the USDA Brief Food Security Survey (food security)
11. Administer and record healthcare utilization survey, adapted from the California Statewide Survey on Homelessness
12. Administer and record health conditions and functional status survey, adapted from the California Statewide Survey on Homelessness
13. Administer and record Short-Form 12 v2 (physical health)
14. Administer and record Kessler 6 (psychological health)
15. Administer and record the Generalized Self-Efficacy Scale (self-efficacy)
16. Administer and record the Brief Resilience Scale (resilience)
17. Administer and record the Perceived Stress Scale (perceived stress)
18. Administer and record the Confusion, Hubbub and Order Scale (household chaos)
19. Administer and record the Future Scale (aka the Adult Hope Scale) (agency)

10.9 12-Month Qualitative Interview Assessment (between months 6-12, subset of 40 participants)

1. Record any Adverse Experiences
2. Conduct semi-structured interview on impact of homelessness and guaranteed income (if applicable) on household strain and well-being, decision-making, time scarcity and future planning

10.10 24-Month Qualitative Interview Assessment (between months 18-24, subset of 40 participants)

1. Record any Adverse Experiences

2. Conduct semi-structured interview on impact of homelessness and guaranteed income (if applicable) on household strain and well-being, decision-making, time scarcity and future planning

10.11 Early Withdrawal Visit/Assessment

1. Record any Adverse Experiences
2. Concomitant interventions review
3. Record household composition data (number of household members and children).
4. Administer and record current housing situation and history of homelessness instruments, adapted from the Family Options Study and the California Statewide Survey on Homelessness.
5. Administer and record income and employment survey, adapted from the California Statewide Survey on Homelessness.
6. Record concomitant interventions in terms of receipt of assistance from other housing, social, and economic assistance programs.
7. Administer and record monthly expenditure amounts and categories, adapted from the Survey of Income and Participation.
8. Administer and record Financial Well-Being Scale, adapted from the Consumer Financial Protection Bureau (financial well-being).
9. Administer and record Material Hardship Survey, adapted from the Urban Institute Well-Being and Basic Needs and the Survey of Income and Program Participation (material hardship)
10. Administer and record the USDA Brief Food Security Survey (food security)
11. Administer and record healthcare utilization survey, adapted from the California Statewide Survey on Homelessness
12. Administer and record health conditions and functional status survey, adapted from the California Statewide Survey on Homelessness
13. Administer and record Short-Form 12 v2 (physical health)
14. Administer and record Kessler 6 (psychological health)
15. Administer and record the Generalized Self-Efficacy Scale (self-efficacy)
16. Administer and record the Brief Resilience Scale (resilience)
17. Administer and record the Perceived Stress Scale (perceived stress)
18. Administer and record the Confusion, Hubbub and Order Scale (household chaos)
19. Administer and record the Future Scale (aka the Adult Hope Scale) (agency)

11 ADVERSE EXPERIENCE REPORTING AND DOCUMENTATION

11.1 Adverse Events

The study team will probe, via discussion with the participant, for the occurrence of adverse events (AEs) during each participant visit and record the information in the site's

source documents. Adverse events will be recorded in the patient CRF. Adverse events will be described by duration (start and stop dates and times), severity, outcome, treatment and relation to study intervention, or if unrelated, the cause. For this study, the primary potential adverse events of concern associated with the study intervention are potential loss of existing public benefits and assistance among participants, and increased income tax burden, similar to the risks that would be incurred by the general population in daily life who might experience a similar increase in overall household income.

12 DISCONTINUATION AND REPLACEMENT OF PARTICIPANTS

12.1 Early Discontinuation of Study Intervention

A participant may discontinue receipt of the study intervention (guaranteed income) and participation in the evaluation activities at any time if the participant, investigator, or sponsor feel that it is not in the participant's best interest to continue. The following is a list of possible reasons for study treatment discontinuation:

- Participant withdrawal of consent (or assent)
- Adverse event that in the opinion of the investigator would be in the best interest of the participant to discontinue study treatment
- Lost to follow-up
- Sponsor request for early termination of study

If a participant is withdrawn from treatment due to an adverse event, the participant will be followed and treated by the Investigator, study team, and community partners until the issue has resolved or stabilized (i.e., assistance applying for additional public benefits, assistance programs, and/or social services from local, county, state, and federal entities in case of the loss of benefits).

All participants who discontinue the study intervention will be encouraged to undergo an early discontinuation visit/assessment as soon as possible and then should be encouraged to complete all remaining scheduled assessments if possible.

All participants are free to withdraw from participation at any time, for any reason, specified or unspecified, and without prejudice.

Reasonable attempts will be made by the investigator to provide a reason for participant withdrawals. The reason for the participant's withdrawal from the study will be specified in the participant's source documents. Refer to Section 10 for early termination assessment procedures.

12.2 Withdrawal of Participants from the Study

A participant may withdraw from the study at any time if the participant, investigator or sponsor feel that it is not in the participant's best interest to continue. All participants are free to withdraw from participation at any time, for any reason, specified or unspecified, and without prejudice.

Reasonable attempts will be made by the investigator to provide a reason for participant withdrawals. The reason for the participant's withdrawal from the study will be specified

in the participant's source documents. As noted above, participants who discontinue study treatment early (i.e., they withdraw prior to the end of the 36-month study period) should have an early discontinuation assessment. Refer to Section 10 for early termination procedures assessment. Participants who withdraw after Visit/Assessment 4 but prior to Visit 5 should be encouraged to come in for a final visit (and the procedures to be followed would include those for their next scheduled visit).

12.3 Replacement of Participants

Participants who withdraw from the study intervention will not be replaced.

Participants who withdraw from the study will not be replaced.

12.4 Study Interruptions Due to Specific Circumstances

a) If the participant is no longer able to act as a payee for guaranteed income due to incarceration, we will contact the designated secondary payee for recruitment, consent, and enrollment as a study participant so that they may continue survey and interview assessments on behalf of the household. Additionally, our community partners will transfer any remaining guaranteed income payments to the secondary payee so that households will continue to receive the income.

b) In case of family separation, guaranteed income payments will continue to the adult who continues to reside with the children in the household.

c) If families move out of Santa Clara County during the study period, they will be eligible to continue to participate in the study and will be eligible to continue to receive the guaranteed income periods for the duration of the study period as long as their contact information remains up to date. This is because moving from the area may be a positive outcome enabled by receipt of public assistance, benefits, and/or the guaranteed income that would be relevant to ascertain for the purpose of the study.

d) If participants opt for early withdrawal from the study (i.e., participating in the surveys and interviews), they will still be eligible to receive guaranteed income payments as a form of economic assistance provided by the community partners. However, only participants who consent and enroll in the study will be eligible for initial randomization.

13 PROTOCOL VIOLATIONS

A protocol violation occurs when the participant, investigator, or Sponsor fails to adhere to significant protocol requirements affecting the inclusion, exclusion, participant safety and primary endpoint criteria. Protocol violations for this study include, but are not limited to, the following:

- Failure to meet inclusion/exclusion criteria

Failure to comply with Good Clinical Practice (GCP) guidelines will also result in a protocol violation. The Sponsor will determine if a protocol violation will result in withdrawal of a participant.

When a protocol violation occurs, it will be discussed with the investigator and a Protocol Violation Form detailing the violation will be generated. This form will be signed by a Sponsor representative and the Investigator. A copy of the form will be filed in the site's regulatory binder and in the Sponsor's files.

14 STATISTICAL METHODS AND CONSIDERATIONS

Prior to the analysis of the final study data, a detailed Statistical Analysis Plan (SAP) will be written describing all analyses that will be performed. The SAP will contain any modifications to the analysis plan described below.

14.1 Data Sets Analyzed

All participants who are enrolled, complete a baseline assessment, are randomized, and, for the intervention group, agree to receive GI payments will be included in the modified intention-to-treat analyses. The primary dataset used will be data prospectively collected by the study team via the use of survey instruments and structured interviews as outlined here. We will obtain complementary administrative data on housing status, housing assistance, housing service use, social service use, and health care service use from the Santa Clara Office of Supportive Housing (Homeless Management Information System), Santa Clara Valley Medical Center Hospital & Clinics (Santa Valley Medical Center HealthLink), Santa Clara County Public Health, County of Santa Clara Social Services Agency (including the Department of Employment and Benefit Services), and from community partners (Destination: Home SV, ¡Sí Se Puede! Collective, Sacred Heart Community Service).

14.2 Demographic and Baseline Characteristics

We will summarize the following demographic variables and characteristics at baseline by group assignment: age, gender, race/ethnicity, education, housing status, housing quality/condition, employment, income, financial well-being, material hardship, food security, household composition, health conditions, functional status, healthcare utilization, social service utilization, agency, self-efficacy, perceived stress, household environment.

14.3 Analysis of Primary Endpoint

We will conduct modified intention-to-treat analyses to assess our primary endpoint, differences in numbers of days spent homeless using Poisson regression.

Analyses will be adjusted for key demographic and clinical characteristics, including: a) referring organization; b) subtype of homelessness; c) preferred payment disbursement schedule (monthly vs hybrid), as well as for covariates that remain unbalanced across the control and intervention groups after randomization. For missing data, we will use multiple imputation, and will employ the last observation carried forward (LOCF), as a sensitivity analysis to assess the robustness of our multiple imputation approach.

14.4 Analysis of Secondary Endpoints

We will conduct intention-to-treat analyses to assess our secondary endpoints, using Cox proportional hazards, logistic and linear regression models as appropriate to the endpoint of interest. Analyses will be adjusted for key demographic and clinical characteristics, as well as for covariates that remain unbalanced across the control and intervention groups after randomization. As sensitivity analyses, we will also conduct per protocol analyses for both our primary and secondary endpoint measures. For missing data, we will employ multiple imputation and use the last observation carried forward (LOCF) as a sensitivity analysis to assess the robustness of the LOCF approach.

For our qualitative assessments, we will use a thematic approach with simultaneous data collection and analysis based on modified grounded theory methodologies. We will review interview transcripts and initial analytic memos to develop a preliminary codebook, code transcripts and iteratively discuss with the study team to add or revise existing codes, have two reviewers independently review transcripts and conduct coding, and hold regular study team meetings to discuss emergent themes until reaching consensus.

14.5 Interim Analysis

We do not plan to conduct any interim analyses.

14.6 Sample Size and Randomization

Up to 300 eligible participants will be randomly assigned to the guaranteed income group (intervention) or usual care (control group) using a computer-generated randomization scheme developed by the study team. Eligible participants will be referred by the community partners to the study team for consent and enrollment into the study prior to randomization. Once participants are enrolled, they will be randomly assigned to either the intervention or control group. Group assignments will be known to our community partners, who are administering the guaranteed income intervention; however, the study team (investigators and research staff) will be blinded to group assignments.

For our primary endpoint, number of days experiencing homelessness, given our sample size of 300 with 150 participants in each arm, we estimate that we will have 80% power at a two-sided significance level of 0.05 to detect a mean reduction of 24.0 days in the intervention group, assuming a mean of 52.3±74.0 days experiencing homelessness from prior studies. Allowing for a 27% dropout rate as estimated from prior studies (for a total of sample size of 220 participants with 110 families in each arm), we will still have 80% power at a two-sided significance level of 0.05 to detect a mean reduction of 28.0 days in the intervention group.

15 DATA COLLECTION, RETENTION AND MONITORING

15.1 Data Collection Instruments

The Investigator will prepare and maintain adequate and accurate source documents designed to record all observations and other pertinent data for each participant treated with the study intervention.

Study personnel at each site will enter data from source documents corresponding to a participant's visit into the protocol-specific electronic Case Report Form (eCRF) OR paper CRF when the information corresponding to that visit is available. Participants will not be identified by name in the study database or on any study documents to be collected by the Sponsor (or designee), but will be identified by a site number, participant number and initials.

For eCRFs: If a correction is required for an eCRF, the time and date stamps track the person entering or updating eCRF data and creates an electronic audit trail. *For paper CRFs:* If a correction is made on a CRF, the study staff member will line through the incorrect data, write in the correct data and initial and date the change.

The Investigator is responsible for all information collected on participants enrolled in this study. All data collected during the course of this study must be reviewed and verified for completeness and accuracy by the Investigator. A copy of the CRF will remain at the Investigator's site at the completion of the study.

15.2 Data Management Procedures

The data will be entered into a validated database. The Data Management group will be responsible for data processing, in accordance with procedural documentation. Database lock will occur once quality assurance procedures have been completed.

All procedures for the handling and analysis of data will be conducted using good computing practices meeting FDA guidelines for the handling and analysis of data for clinical trials.

15.3 Data Quality Control and Reporting

After data have been entered into the study database, a system of computerized data validation checks will be implemented and applied to the database on a regular basis. The study database will be updated in accordance with the resolved queries. All changes to the study database will be documented.

15.4 Archival of Data

The database is safeguarded against unauthorized access by established security procedures; appropriate backup copies of the database and related software files will be maintained. Databases are backed up by the database administrator in conjunction with any updates or changes to the database.

At critical junctures of the protocol (e.g., production of interim reports and final reports), data for analysis is locked and cleaned per established procedures.

15.5 Availability and Retention of Investigational Records

The Investigator must make study data accessible to the monitor, other authorized representatives of the Sponsor (or designee), IRB/IEC, and Regulatory Agency (e.g., FDA) inspectors upon request. A file for each participant must be maintained that includes the signed Informed Consent, HIPAA Authorization and Assent Form and copies of all source documentation related to that participant. The Investigator must ensure the

reliability and availability of source documents from which the information on the CRF was derived.

All study documents (patient files, signed informed consent forms, copies of CRFs, Study File Notebook, etc.) must be kept secured for a period of two years following marketing of the investigational product or for two years after centers have been notified that the IND has been discontinued. There may be other circumstances for which the Sponsor is required to maintain study records and, therefore, the Sponsor should be contacted prior to removing study records for any reason.

15.6 Monitoring

Monitoring visits will be conducted by representatives of the Sponsor according to the U.S. CFR Title 21 Parts 50, 56, and 312 and ICH Guidelines for GCP (E6). By signing this protocol, the Investigator grants permission to the Sponsor (or designee), and appropriate regulatory authorities to conduct on-site monitoring and/or auditing of all appropriate study documentation.

15.7 Participant Confidentiality

In order to maintain participant confidentiality, only a site number, participant number and participant initials will identify all study participants on CRFs and other documentation submitted to the Sponsor. Additional participant confidentiality issues (if applicable) are covered in the Clinical Study Agreement.

16 ADMINISTRATIVE, ETHICAL, REGULATORY CONSIDERATIONS

The study will be conducted according to the Declaration of Helsinki, Protection of Human Volunteers (21 CFR 50), Institutional Review Boards (21 CFR 56), and Obligations of Clinical Investigators (21 CFR 312).

To maintain confidentiality, all laboratory specimens, evaluation forms, reports and other records will be identified by a coded number and initials only. All study records will be kept in a locked file cabinet and code sheets linking a patient's name to a patient identification number will be stored separately in another locked file cabinet. Clinical information will not be released without written permission of the participant, except as necessary for monitoring by the FDA. The Investigator must also comply with all applicable privacy regulations (e.g., Health Insurance Portability and Accountability Act of 1996, EU Data Protection Directive 95/46/EC).

16.1 Protocol Amendments

Any amendment to the protocol will be written by the Sponsor. Protocol amendments cannot be implemented without prior written IRB/IEC approval except as necessary to eliminate immediate safety hazards to patients. A protocol amendment intended to eliminate an apparent immediate hazard to patients may be implemented immediately, provided the IRBs are notified within five working days.

16.2 Institutional Review Boards and Independent Ethics Committees

The protocol and consent form will be reviewed and approved by the IRB/IEC of each participating center prior to study initiation. Serious adverse experiences regardless of causality will be reported to the IRB/IEC in accordance with the standard operating procedures and policies of the IRB/IEC, and the Investigator will keep the IRB/IEC informed as to the progress of the study. The Investigator will obtain assurance of IRB/IEC compliance with regulations.

Any documents that the IRB/IEC may need to fulfill its responsibilities (such as protocol, protocol amendments, Investigator's Brochure, consent forms, information concerning patient recruitment, payment or compensation procedures, or other pertinent information) will be submitted to the IRB/IEC. The IRB/IECs written unconditional approval of the study protocol and the informed consent form will be in the possession of the Investigator before the study is initiated. The IRB/IECs unconditional approval statement will be transmitted by the Investigator to the Sponsor or designee prior to the shipment of study supplies to the site. This approval must refer to the study by exact protocol title and number and should identify the documents reviewed and the date of review.

Protocol and/or informed consent modifications or changes may not be initiated without prior written IRB/IEC approval except when necessary to eliminate immediate hazards to the patients or when the change(s) involves only logistical or administrative aspects of the study. Such modifications will be submitted to the IRB/IEC and written verification that the modification was submitted and subsequently approved should be obtained.

The IRB/IEC must be informed of revisions to other documents originally submitted for review; serious and/or unexpected adverse experiences occurring during the study in accordance with the standard operating procedures and policies of the IRB; new information that may affect adversely the safety of the patients of the conduct of the study; an annual update and/or request for re-approval; and when the study has been completed.

16.3 Informed Consent Form

Informed consent will be obtained in accordance with the Declaration of Helsinki, ICH GCP, US Code of Federal Regulations for Protection of Human Participants (21 CFR 50.25[a,b], CFR 50.27, and CFR Part 56, Subpart A), the Health Insurance Portability and Accountability Act (HIPAA, if applicable), and local regulations.

The Investigator will prepare the informed consent form, assent and HIPAA authorization and provide the documents to the Sponsor or designee for approval prior to submission to the IRB/IEC. The consent form generated by the Investigator must be acceptable to the Sponsor and be approved by the IRB/IEC. The written consent document will embody the elements of informed consent as described in the International Conference on Harmonisation and will also comply with local regulations. The Investigator will send an IRB/IEC-approved copy of the Informed Consent Form to the Sponsor (or designee) for the study file.

A properly executed, written, informed consent will be obtained from each participant prior to entering the participant into the trial. Information should be given in both oral and written form and participants (or their legal representatives) must be given ample opportunity to inquire about details of the study. If appropriate and required by the local

IRB/IEC, assent from the participant will also be obtained. If a participant is unable to sign the informed consent form (ICF) and the HIPAA authorization, a legal representative may sign for the participant. A copy of the signed consent form (and assent) will be given to the participant or legal representative of the participant and the original will be maintained with the participant's records.

16.4 Publications

The preparation and submittal for publication of manuscripts containing the study results shall be in accordance with a process determined by mutual written agreement among the study Sponsor and participating institutions. The publication or presentation of any study results shall comply with all applicable privacy laws, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996.

16.5 Investigator Responsibilities

By signing the Agreement of Investigator form, the Investigator agrees to:

1. Conduct the study in accordance with the protocol and only make changes after notifying the Sponsor (or designee), except when to protect the safety, rights or welfare of participants.
2. Personally conduct or supervise the study (or investigation).
3. Ensure that the requirements relating to obtaining informed consent and IRB review and approval meet federal guidelines, as stated in § 21 CFR, parts 50 and 56.
4. Report to the Sponsor or designee any AEs that occur in the course of the study, in accordance with §21 CFR 312.64.
5. Ensure that all associates, colleagues and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.
6. Maintain adequate and accurate records in accordance with §21 CFR 312.62 and to make those records available for inspection with the Sponsor (or designee).
7. Ensure that an IRB that complies with the requirements of §21 CFR part 56 will be responsible for initial and continuing review and approval of the clinical study.
8. Promptly report to the IRB and the Sponsor (or designee) all changes in the research activity and all unanticipated problems involving risks to participants or others (to include amendments and IND safety reports).
9. Seek IRB approval before any changes are made in the research study, except when necessary to eliminate hazards to the patients/participants.
10. Comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements listed in § 21 CFR part 312.

APPENDIX 1. SCHEDULE OF STUDY SURVEY ASSESSMENTS

	Intervention Period					Post-Intervention Period		
	Assessment #1 (Baseline)	Assessment #2 (6 Months)[a]	Assessment #3 (12 Months)[a]	Assessment #4 (18 Months)[a]	Assessment #5 (24 Months)[a]	Assessment #6 (27 Months)[a]	Assessment #7 (30 Months)[a]	Assessment #8 (36 Months)[a]
Informed Consent	X							
Adverse Experiences	X	X	X	X	X	X	X	X
Demographic data	X							
Household composition	X	X	X	X	X	X	X	X
Current housing situation	X	X	X	X	X	X	X	X
History of homelessness	X							
Income, employment, benefits	X	X	X	X	X	X	X	X
Social services and assistance	X	X	X	X	X	X	X	X
Monthly expenditures	X	X	X	X	X	X	X	X
Financial well-being	X	X	X	X	X	X	X	X
Material hardship	X	X	X	X	X	X	X	X
Food security	X	X	X	X	X	X	X	X
Healthcare utilization	X	X	X	X	X	X	X	X
Health conditions and functional status	X	X	X	X	X	X	X	X
Physical health (SF-12 v2)	X	X	X	X	X	X	X	X
Kessler 6 (psychological health)	X	X	X	X	X	X	X	X
Generalized Self-Efficacy Scale	X	X	X	X	X	X	X	X
Brief Resilience Scale	X	X	X	X	X	X	X	X
Perceived Stress Scale	X	X	X	X	X	X	X	X
Confusion, Hubbub and Order Scale	X	X	X	X	X	X	X	X
Semi-Structured 1-on-1 Interviews			X		X			X

[a] ±4 weeks

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