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Study Protocol

(Amended 10.28.2020)

TABLE OF CONTENTS

Study Title:	UCLA WPC-LA Transition Age Youth (TAY) Reentry Study
Study Site:	UCLA
Other Sites and/or Collaborators:	Los Angeles (LA) County Health Agency and Los Angeles (LA) County Probation Department
Key Words:	juvenile reentry, substance abuse disorders, intervention, adolescent health, social networks

I. Funding

The research study is funded by the National Institutes of Health (NIH)—National Institute on Drug Abuse (NIDA) through a K23 Career Development Award and a grant from the California Community Foundation (CCF) to Dr. Barnert.

II. Lay Summary

The proposed study intervention, UCLA WPC-LA Transition Age Youth (TAY) Reentry Study, adapts the successful evidence-based adult Transitions Clinic model to youth. We hypothesize that re-wiring adolescent social networks during community reentry can potentially break the vicious cycle of adolescent substance use and youth incarceration.

To test our hypothesis, we are collaborating closely with the LA County Health Agency and the Probation Department to develop and measure the impact of a network coach intervention (termed "Whole Person Care (WPC)" by DHS) to reduce adolescent substance use and other markers of healthy reintegration among recently incarcerated adolescents. We will also test the potential mechanism of enhanced social networks during reentry as mediating youths' success in reducing substance use.

We will invite 200 youth to participate: 160 transition age youth (TAY) exiting LA County jails (ages 18-24, 80 receiving and 80 not receiving the WPC intervention), and 40 TAY exiting the juvenile justice system (ages 16-19).

This study will use an observational survey research design to understand the interrelationships between social networks, substance use, and care utilization for TAY who transition home following incarceration. A mixture of closed-ended surveys along with open-ended focus group discussions will be used. Participants will be asked to complete three surveys (baseline, as well as 3 and 9 months post-release). For TAY exiting jail, baseline surveys will be conducted while detained. For TAY exiting the juvenile justice system, baseline surveys will be conducted in the community, up to one month after their release from incarceration. From the surveys, the research team will identify participants with high and low health service utilization, and invite them to participate in one focus group interview. Participation in the study will take up to 3 hours, which includes survey completion and focus group participation.

Medical records, with limited information, will also be requested from LA Department of Health Services for adults eligible for the Whole Person Care intervention.

Furthermore, we intend to assess the intervention's fidelity by observing youth-WPC coach interactions and inviting at least 5 WPC coaches to participate in surveys and interviews. This will also help assess the coaches' perceptions of successes and challenges with adherence to the WPC protocol. Coaches will be invited to participate in the study through a separate consent process.

Amendment 05/27/20:

In response to COVID-19, we will conduct monthly qualitative interviews with the 19 participants that are currently enrolled in the study. Interviews will be done over the phone until we are permitted to resume in-person procedures. We will also add an additional time point for when we administer the follow-up survey, 1-month post release.

Amendment 10/28/2020:

Due to the ongoing COVID-19 pandemic, we are now going to be using remote recruitment and consent produces for young people exiting jail and will resume an in-person option as soon as it is safe to do so. The WPC team will provide potential participants with a study authorization form that includes information about the study. If potential participants are interested, they will be required to provide a signature in order have the WPC team share their contact information with the UCLA study team. The UCLA study team will then remotely recruit interested participants and will obtain verbal consent to participate in the study. Because of this, we are changing the times at which the baseline and follow-up surveys are administered. Participants will now complete surveys 2 weeks after release and then two, four, and six months after release.

Background and Significance

Untreated adolescent substance use disorders (SUD) lead to youth incarceration. US law enforcement makes 1.3 million juvenile arrests annually. Of the nearly 51,000 youth in juvenile detention on a given day, 50-88% have SUD. Adolescent SUD are often comorbid with mental health problems, which substantially elevates risk of youth incarceration, and 70% of detained youth report prior trauma exposure, heightening behavioral health risks. Untreated adolescent SUD directly lead to incarceration for drug-related charges and is strongly associated with non-drug offending. Adolescent substance use, mental health disorders, and youth incarceration are highly intertwined.

Incarceration exacerbates existing behavioral health problems, feeding a vicious cycle. The experience of incarceration itself can worsen youths' existing mental health problems, such as depression, and increase future risk of substance use, likely due to the psychological trauma of incarceration and the potential negative social influences within detention settings. Our analyses of the Add Health dataset support a potential causal linkage between incarceration and worse behavioral health outcomes. We found that, compared to no incarceration, youths' lifetime incarceration duration greater than 1 year significantly predicted subsequent adult depression (OR= 2.8) and adult suicidal thoughts (OR= 2.3), controlling for baseline mental health, substance use, and other key covariates. We also found that odds of heavy alcohol use were 9-11 percentage-points higher among incarcerated cases than among non-incarcerated matched controls at an individual's first post-incarceration wave ($p<0.001$); odds of other drug use were 18-26 percentage-points higher ($p<0.001$); and depressive symptoms (CESD-R20) scores were 0.39 – 1.17 points higher ($p<0.001$).

Re-entry, the period when youth transition from detention facilities back to the community, represents a critical juncture and a high-risk period for re-engaging in substance use. In total, 88,000 detained youth are released annually in the US, most of whom are poor and of color. Within 3 years of release, 75% of adolescents are re-arrested, with highest risk among youth with SUD. Adolescent SUD presence and severity strongly predict re-arrest and less time attending school or being employed. Thus, adolescent SUD not only lead directly to incarceration, but also contribute to low educational attainment and future unemployment, which further increase lifetime incarceration risk and perpetuate individual and intergenerational social disadvantage. Furthermore, the risk of mortality in the first 2 weeks after release for adult former prisoners is 3.5 times that of the general adult population, with the leading cause of death being drug overdose, most commonly cocaine, psychostimulants, and opioids. Formerly incarcerated youth similarly demonstrate high premature mortality. Although many youth express plans to reform and to stay "clean" from drugs upon release from detention, the challenges of returning to chaotic and even dangerous home environments while simultaneously transitioning out of probation schools and correctional health systems—all while confronting the normal developmental tasks of adolescence—make healthy reentry extremely difficult without adequate supports and clinical treatments.

Breaking the vicious cycle of adolescent substance use and youth incarceration requires effective linkages to substance use treatment programs during community reentry. Studies have repeatedly demonstrated that behavioral health treatment is effective in treating adolescent SUD and reducing recidivism, and is associated with improved educational and vocational outcomes, yet many recently incarcerated youth fail to access these services. Among recently incarcerated youth with a behavioral health disorder, only 34% access behavioral health services during the 6-month reentry period and receive services an average of only 2 out of every 100 days. Family functional therapy and multisystemic therapy are cost-effective interventions that reduce substance use and recidivism and increase school success and employment. The effectiveness of these services is encouraging, but many youth do not receive these services. All youth, by law, have access to healthcare while incarcerated, but no consistent care is required following release. However, access to regular care often stops when incarceration ends, making reentry a missed opportunity for connecting youth to needed behavioral healthcare. Enhancing youths' connections to effective substance use treatment programs is crucial. Interventions that link reentry youth to substance use treatment need to take into account the unique context of reentry—a time when youth navigate shifts in personal relationships and support networks.

Social networks powerfully influence adolescent substance use and delinquent behavior—and reentry is a natural time to re-set social networks. Strong evidence indicates that adolescents' substance use is closely tied to the behaviors and attitudes of individuals in their social network. As described by Social Influence Theory, social network structure and composition are shaped by cultural and environmental factors. In the reentry context, these factors include, for example, policies that dictate probation monitoring regarding who adolescents can associate with. Social networks then determine sources of support, transmission of social norms, and access and opportunity to engage in substance use. Although peers are powerful points of influence during adolescence, relationships with supportive adults can protect against substance use.

Despite great interest in social networks as potential determinants of risky behaviors, we have yet to fully characterize the causal pathways linking social networks with adolescent health. Studies suggest that changes in social networks can impact substance use, but little is known about how to harness this relationship effectively. Answering this question may have

applications across many social environments and health domains. Interventions that re-wire social networks might offer a relatively low-cost, self-sustaining, and effective means to prevent some of the most challenging behaviors that lead to poor health outcomes.

III. Hypothesis and Specific Aims

This community-partnered study seeks to explore, describe, and measure the implementation and impact of an innovative pilot intervention, the Whole Person Care (WPC) Program, a network coach intervention that addresses two key challenges for recently incarcerated youth: poor care coordination in the "behavioral health cascade" and need for more positive support from the social network. Los Angeles (LA) County has the largest justice system in the US and has begun implementing the WPC network coach intervention to enhance linkages to community behavioral health services. WPC is based on the successful Transitions Clinic model, an intervention with demonstrated efficacy in linking recently incarcerated adults to needed healthcare and improving health outcomes. The model has yet to be implemented for reentry youth, but has the potential to be transformative at the critical developmental stage of adolescence, when peer social networks are highly dynamic and youth behaviors can affect lifelong trajectories. WPC network coaches will receive formalized training modeled after the adult Transitions Clinic approach and will serve as a formerly incarcerated adult role model who provides care coordination and social support to facilitate access to needed behavioral health services. Tailored for reentry youth, WPC will also include a social network component whereby coaches are trained to actively guide youth toward pro-social peers and adults. The Principal Investigator, Elizabeth Barnert, has been working closely with LA County and this study capitalizes on a unique opportunity to study the WPC program. We propose an exploratory and observational study of WPC, using a community-partnered, participatory research (CPPR) approach. While we anticipate that this data collection and analysis will have sufficient power to detect differences between groups, the relative paucity of information known about this topic and this study population ensure that the data collected will be novel and provide an opportunity to inform intervention design and refinement.

Specific aims are to:

1) Describe the social networks of transition-age youth (TAY) exiting jail or juvenile detention.

Hypothesis 1: Participants will describe their social networks. We expect that social networks will include individuals who have a history of substance use, as well as individuals who do not have a history of substance use and/or discourage the use of substances.

2) Measure the impact of the Whole Person Care (WPC) intervention for TAY exiting jail in decreasing rates of 30-day use and risky use of marijuana and alcohol.

Hypothesis 2: Incarcerated youth enrolled in the WPC intervention will have less substance use 3 and 9 months post-release compared to their peers who are not receiving the WPC intervention.

3) Test whether the WPC intervention decreases recidivism and increases receipt of behavioral health services (secondary outcomes).

Hypothesis 3: Youth participating in WPC will have less recidivism and higher rates of receipt of behavioral health services.

4): Examine whether recently incarcerated youth receiving the WPC intervention report healthier social networks (lower proportion of peers engaging in risky behaviors and a higher number of supportive adults) than control youth.

Hypothesis 4: Youth receiving the WPC intervention will have a lower proportion of peers engaging in substance use and a higher number of supportive adults in their social networks compared to their peers in the control group.

5) Identify effective approaches for achieving linkages to care during reentry for TAY who have high community health service utilization versus low community health service utilization.

Hypothesis 5: TAY will describe the interrelationship between social networks, substance use, and care utilization, providing insight that can guide the development and implementation of a social network intervention to reduce TAY substance use during reentry.

IV. Research Design and Methods

We will use a community-partnered participatory research (CPPR) approach, collaborating closely with the LA County Health Agency and the Probation Department to develop and measure the impact of a network coach intervention to reduce adolescent substance use and other markers of healthy reintegration among recently incarcerated adolescents. We will conduct an observational study to help us gain insight of the intervention, including the implementation and study population. Note: There are two populations in this study: (1) Transition age youth (TAY), ages 18-24, exiting the adult criminal system and (2) TAY, ages 16-19, exiting the juvenile justice system. Study methods for each population are described below, starting with the adult population.

****TAY Exiting the Adult Criminal System (ADULT POPULATION)****

Study population:

Participants who are eligible for the Whole Person Care—Los Angeles (WPC-LA) Reentry post-release program will be eligible for the adult population of this study. The WPC Reentry program, implemented by the Los Angeles County Health Services Department, links jail inmates with community-based health, behavioral health, and social service providers as they return to the community. The intervention connects participants to Community Health Workers (CHWs) with a prior personal history of incarceration. CHWs assist participants in engaging with community-based health, behavioral health, and social service providers during reentry to the community. Services provided include mentorship and social support; health and social service navigation; linkage to housing, employment, education, legal assistance and social supports; accompaniment to key health and behavioral health appointments; assistance with adherence to appointments, treatments and medications; and connection to transportation. The mentorship and social support aspects of the intervention will indirectly target the social networks of participants. The WPC intervention is an existing intervention. The WPC intervention enrolls 750 individuals per month across LA County; approximately 12% are transition age youth ages 18-24. Participants are invited to this program while detained by the WPC case manager. Thus, WPC is a voluntary program. The WPC case manager is responsible for determining eligibility for the WPC reentry program and enrollment in the WPC program, not the research staff.

Recruitment and Consent:

We will recruit 160 adults exiting the LA county justice system – 80 who have enrolled in the WPC program and 80 have not. We anticipate enrolling participants over an approximate 9 month window, aiming to recruit about 9 individuals per arm (WPC and non-WPC) each month. This represents approximately 10% of the eligible population each month for each arm.

Potential subjects will be identified as follows: (1) The research associate (RA) will shadow the WPC case manager as she invites participants to enroll in WPC. (2) The RA will then approach and ask potential WPC participants if they are interested in participating in the study, regardless of whether they accept to enroll in the WPC program or not. If the participant opts in to the WPC intervention, he/she will be placed in the "intervention" group of the study; if the participant opts out of the WPC intervention, he/she will be placed in the "non-intervention" group of the study. (3) If the participant is interested in participating in the study, the RA will confirm the age of the participant (must be between the ages of 18-24) and assess whether there are no severe cognitive delays based on communication with the participant.

If eligible, the RA will review the study with the interested participant and obtain written consent. Furthermore, the RA will obtain a signed HIPAA authorization form for research for medical record access to allow for later record review and abstraction. The RA will remind the participant of the voluntary nature of the study and that participation in no way affects their standing with the Court, the Sheriff's department, or their receipt of WPC.

Data Collection:

The RA will administer the baseline survey in a private area where respondents' answers cannot be overheard. Surveys have been piloted with TAY not in jail and take an average of 20 minutes to complete. Upon completion of the survey, the RA will ask for a telephone number and address to contact the participant after their release from incarceration. This information will be kept separate from the survey. To encourage follow-up, a $50 cash or gift card incentive (based on participant's preference) will be given to participants if they contact the research team after their release. At this time, participants will also be provided with a copy of the consent and HIPAA authorization forms.

Follow-up surveys will be conducted at 3 and 9 months post-release. These surveys will be conducted in-person or over the phone, based on participant's preference, and are expected to last up to 30-minutes each. A $50 gift card or cash incentive will be given after the completion of each follow-up survey.

Following study subject involvement (completion of surveys), medical record abstraction will be completed in partnership with LA County. We anticipate that this will be completed via a systematic data pull that includes information for all study participants that have signed a HIPAA authorization form. Thus, no abstraction form is included. Chart data will include: arrests, time spent incarcerated, recidivism, health services utilization – such as hospitalization and treatment, health diagnoses, as well as uptake / utilization of the WPC program. This information, in conjunction with data collected via survey administration, will be used both as covariates to help control for any difference between the intervention and control groups as well as for outcomes data related to behavioral health uptake and recidivism.

Amendment 5/27/20:

Qualitative Interviews and Follow-up Survey

Due to COVID-19 pandemic, we are suspending all in-person procedures until allowed to resume. During this time, we will be conducting up to 9 monthly qualitative interviews over the phone with the 19 participants who are currently enrolled in the study; we have also added another time point for when the follow-up survey will be administered: 1 month after release. We have created an addendum consent and those participants that are currently enrolled will be asked, over the phone or in-person when permissible, whether or not they are interested in participating in the new study procedures. If they are interested, the RA will obtain verbal consent. Participants will receive $25 for each of the qualitative interviews completed. They will also receive $50 for completing the additional follow-up survey.

Amendment 10/28/20:

Recruitment and Consent:

In order to minimize in-person contact due to the COVID-19 pandemic, we are not going to recruit and consent participants remotely. We will resume an in-person option when it is safe to do so. The WPC team will identify potential participants who are about to exit jail and will provide them with the study authorization form that includes information about the study. If potential participants are interested in participating in the study, they must sign the study authorization form that would allow the WPC team to share their name and contact information with the UCLA study team. Once the UCLA study team receives this information, a research assistant will then contact potential participants and continue with remote recruitment procedures. If eligible, the RA will review the study with the interested participant and obtain verbal consent. The RA will remind the participant of the voluntary nature of the study and that participation in no way affects their standing with the Court, the Sheriff's department, or their receipt of WPC.

Data Collection:

The RA will administer the baseline survey, over the phone, 2 weeks after release in a private area where respondents' answers cannot be overheard. The survey will take approximately 30 minutes to complete. The RA will also conduct follow-up surveys two, four, and six months after release. Participants will receive $50 for each survey that is completed, for a total of up to $200. During the COVID-19 pandemic, to minimize in-person contact, participants will have the option of receiving these incentives through the mail or through payment apps (Venmo, Zelle, CashApp, etc.), depending on their preference. Once it is safe to do so, we will also allow for in-person delivery options.

Previously, our study team was going to be performing chart abstractions from LA Department of Health Services records for those enrolled in the Whole Person Care initiative, but we have chosen to not move ahead with this. We will no longer be asking study participants to sign HIPAA authorization forms.

****TAY Exiting the Juvenile Justice System (JUVENILE POPULATION)****

Recruitment and Consent:

We will recruit 40 youth exiting the juvenile justice system.

Potential subjects will be identified as follows: (1) the Los Angeles County Department of Probation will provide the research team the names and contact information of youth ages 16 to 19 exiting incarceration and returning home to the Centinela Valley of Los Angeles, California. A weekly list of names and telephone numbers will be emailed via a protected excel file. Probation will also give youth returning home a flyer informing them of the study. (2) The study team will review the list provided by Probation to identify those that may be eligible based on age and zip code. (3) The Office of the Head Public Defender will contact youths to notify them of the study, utilizing the scripted Study Information Sheet, and ask if the youth would provide permission for being contacted by the UCLA study team. (4) If the youth provides permission for contact for the study, the Public Defender will notify the UCLA study team. The RA will then call the numbers provided and determine eligibility (i.e. between the ages of 16 and 19, fluent in English or Spanish, living in the Centinela Valley, no severe cognitive delay). (5) If the youth is interested and eligible, verbal assent and parental permission will be obtained (note: youth ages 18 years of age and older can provide consent). The PI has experience with this method of data collection (UCLA IRB application: 15-001698). Wards of the state will not be invited to participate.

Data Collection:

The RA will administer the baseline survey over the phone or in-person, depending on participant's preference. Surveys have been piloted with TAY not in jail and take an average of 20 minutes to complete. Upon completion of the survey, the RA will mail a $50 gift card or cash incentive, based on participant's preference, to compensate them for their time. Copies of the parental permission and assent or consent will be provided to the participants' along with the study incentive. Follow-up surveys will be conducted at 3 and 9 months post-release. These surveys will be conducted in-person or by phone, based on participant's preference, and are expected to last up to 30-minutes each. A $50 gift card or cash incentive will be given after the completion of each follow-up survey.

FOCUS GROUPS

The research team will also invite a sub-set of survey participants from the Centinela Valley (eligible zip codes included as an attachment) to participate in focus groups outside of detention. Participants will be asked to participate in one focus group, lasting up to one-hour. Based on survey results, focus groups will be purposefully designed to include groups with individuals who are high versus low care utilizers. Utilization rates will be determined based on both youth survey responses and medical record abstraction. These rates will then be reviewed by the study data analyst and investigators to determine the appropriate cut point for the dichotomization of health services utilization. Two focus groups will be conducted with TAY who exited the county jail and two other focus groups will be conducted with youth who were released from the juvenile justice system.

<u>Time required of subjects:</u>

Total time: up to 3 hours

Recruitment and consent: 10 minutes

Baseline survey: 30 minutes

3-month follow-up survey: 30 minutes

6-month follow-up survey: 30 minutes

Focus group interview: 60 minutes (optional)

Fidelity of the Intervention:

We will utilize 2 methods for assessing fidelity of the intervention: 1) Youth surveys: the follow-up youth surveys for those in the intervention group will include a WPC fidelity form to assess whether core components of the intervention occurred, including measuring the frequency and duration of interactions with coaches, youths' perceptions of coaches and the usefulness of the WPC program. 2) Coach surveys and interviews: Network coaches will complete a WPC fidelity form (survey) and we will conduct qualitative interviews with network coaches to assess their perceptions of successes and challenges with adherence to the WPC protocol. Only interviews with coaches will be audio recorded. Coaches will have the opportunity to listen, edit, and delete the recordings. These assessments will provide information for refinement of the intervention and pilot data to inform the R01 submission.

Statistics and Data Analysis

For the main outcome, percentage of days used marijuana in the last 30 days (Aim 2), we will conduct a linear mixed effects regression model to account for repeated measurements within individual youth. We will perform unadjusted and adjusted comparisons, controlling for baseline demographic (race/ethnicity, age, parental SES) and substance use characteristics, as well as any variables found to be differential between the intervention and control groups. Similar analyses will be carried out to examine the impact of Whole Person Care (WPC) on percentage days used alcohol, and risky use of marijuana and alcohol. Risky alcohol use will be defined using the Edelen (2009) measure of Adolescent Alcohol Misuse, which has also been adapted for use with marijuana (Dudovitz, 2019). The index assesses behaviors in the prior 12 months and ranges from 0–8, with higher scores representing more risky substance use. For each of the secondary outcomes, recidivism and receipt of SUD and mental health services (Aim 3), we will conduct generalized linear mixed effects regression models to account for repeated measurements within individual youth, while controlling for baseline demographic and SUD characteristics. We will also evaluate whether there is effect modification by baseline mental health symptoms, using interaction terms with the exposure variable in the regression analysis. Additionally, if analyses for Aims 2 and Aim 3 do not indicate improvement overall in the intervention group, we will conduct exploratory analyses to identify subgroups of youth whose Aim 2 and Aim 3 outcomes improve and examine their social networks.

Using the quantitative surveys, we will also conduct a social network analysis, which will help determine why the intervention did or did not demonstrate the expected effect. We will measure how social networks function for youth and whether the insertion of a caring adult can create linkages to substance use services and promote healthier social networks. We will use the approach described in Baron and Kenny (1986) to evaluate whether our data are consistent with a model in which social networks mediate the relationship between WPC receipt and substance use. Primary social network measures will include the change in proportion of peers using substances (alcohol, marijuana, other drugs), limited to those whom the subject interacts with at least weekly. We will compare baseline social network characteristics of the intervention and control groups and control for these measures if significant differences are noted. To test whether youth receiving WPC report a lower proportion of peers in their network engaging in substance use, we will conduct a mixed

effects binomial logistic regression model accounting for repeated measurements within students. We will control for baseline demographic characteristics, as well as any variables found to be differential between the intervention and control groups. Furthermore, we will examine the number of non-using supportive adults in their network using a mixed effects binomial logistic regression model. We will also use mixed effects models to investigate whether network structure differs between study arms and whether intervention youth report stronger connections to healthy peers and adults.

After completion of focus groups, we perform inductive thematic analysis to identify emergent themes. Results will be triangulated with the surveys.

Sample size was determined based on power calculations and the feasibility of the budget in the pending grant. We plan to recruit and consent 160 TAY ages 18-24 exiting the adult criminal justice system and 40 TAY ages 16-19 exiting the juvenile justice system.

V. Characteristics of the Study Population

Maximum number of study participants we hope to enroll: 160 adults exiting the LA county justice system and 40 youth exited the juvenile justice system and 10 coaches/CHWs

Inclusion criteria for TAY exiting the adult criminal system:

1. Age 18-24

2. Fluent in English or Spanish

3. No severe cognitive delay

4. WPC-eligible (eligibility for the WPC program is determined by the WPC team and is outlined under the "Determining Eligibility" paragraph.)

Inclusion criteria for TAY exiting the juvenile justice criminal system:

1. Ages 16-19

2. Fluent in English or Spanish

3. Not a ward of the state through the dependency system. (Note: some participants will be wards of the state through the delinquency system once home due to temporary formal probation monitoring).

4. Reside in the Centinela Valley (eligible zip codes are provided as an attachment)

Inclusion criteria for Focus Group Interviews

1. Survey participants

2. Reside in the Centinela Valley (eligible zip codes are provided as an attachment)

3. High care or low care utilizer as determined by survey responses

Exclusion Criteria:

Exclusion criteria is inverse of inclusion criteria.

Determining Eligibility:

For youth exiting the juvenile justice system, eligibility will be determined by the research associate (RA). After receipt of the list of potential study participants from Probation, the RA will review the list to assess eligibility for age and zip code and will then provide the list of the office of the Head Public Defender, who will contact youth to obtain their permission for UCLA study team contact. Following this, the UCLA RA will contact them and confirm whether the youth is between the ages of 16-19, speaks Spanish or English, and is not a ward of the state (i.e. returned home to a parent). Assessment of cognitive delay will also be conducted by RA.

WPC staff will determine eligibility for the WPC intervention while the participant is detained. After WPC eligibility is confirmed, the research team will determine study eligibility.

Eligibility criteria for the WPC intervention are:

- Involvement with the justice system (pre-booking, probation, or incarceration) within the last 3 months; and
- 1 Emergency Department visit in the past 6 months; or 1 hospital visit in the past 12 months; and
- At least one of the following:
- Chronic medical condition;
- Serious mental illness;
- Substance Use Disorder; or
- Homelessness

Coach/CHW Inclusion Criteria:

- Current network coach/CHW working for WPC
- Coach/CHW consent to participate in study

As long as coaches/CHWs are employed by WPC at the time of the study, are working with a youth, and consent to participate, they will be eligible to participate. Eligibility will be determined by the PI or RA staff.

VI. Study Data and Security

We will be asking subjects detailed information about substance use, mental health, and behavioral health services access. Some behaviors that we will assess are illegal, but we will take several steps to minimize the chances of learning something that would require mandatory reporting.

To minimize the chances of learning something we would need to report, the consent discussions will clearly state things that would trigger reporting and we will make sure youth and parents understand this before moving on. We have also structured our study instruments to avoid collecting information that would ethically require action. We have modified the ACEs (adverse childhood experiences) screen to avoid questions that may reveal a concern for child abuse. We will also remind participants that their participation is completely voluntary and that they may choose to skip any or all questions that they do not feel comfortable answering.

The PI, a licensed clinician (Dr. Elizabeth Barnert, MD, MPH, MS) will be on call in cases where abuse is reported to RAs (i.e., non-clinicians). They can reach me immediately via my email address and/or work phone and cell phone. If I am away, I will notify the RAs in advance and they can direct immediate issues to my primary mentor, Mitch Wong, also a physician. He would similarly be available by email and/or work phone and cell phone.

We do not anticipate that the study will lead to a report of a previously unaddressed reportable disease that requires action by our study team.

WPC and Probation staff will provide the UCLA research team the following information for study recruitment purposes: Names, dates of release, telephone numbers, zip codes and e-mail addresses.

All study data will be coded and personal identifying information will be removed and destroyed. The PI and research assistants will use a unique ID number to identify the subjects' survey and interview data. The link to the subjects' personal identifying information and their ID number will be kept separate in a password protected file.

We will not distribute data to any researchers outside of the study team. We will not distribute data to any individuals outside of the study team.

Contact information received by the Los Angeles Probation Department will be transmitted electronically via an encrypted, password-protected file using the UCLA DGIT secure file transfer system. Data received from the Los Angeles Department of Health Services also be transmitted using the same mechanism or will be transferred via in-person hand-off between WPC contact and study team.

Data will be stored on encrypted, password protected UCLA computers on a secure network server. Only the research team will have access to the data.

Audio files will be securely transmitted via the internet to our HIPAA compliant transcription service. This will be done by uploading the files to a secure, firewall protected web address that can only be accessed by the study team and transcription service. Upon completion of transcription, the transcription service will be asked to promptly destroy all audio files.

After the study is completed, personal identifiers and/or codes linking the data and/or specimens to personal identifiers will be maintained for future research for those participants who have provided prior permission for this. The information will be securely stored by the P.I. on the Divisions secure network server. Only the PI will have access to the link file and file that contains personal identifiers. These will be stored in two separate, password protected documents on the secure server used for the study. The link file will only be used to identify participants for future studies and will be stored separately from any data files so that identifiers will not be linked with survey responses.

Participants may be contacted for future studies (e.g. including collect administrative data from Probation DMH in the future)

Amendment 10/28/20:

Contact information received from the Whole Person Care Program will be transmitted electronically via an encrypted, password-protected file using the UCLA DGIT secure file

transfer system. To protect participant confidentiality, these signed forms will be kept by WPC in a locked cabinet that only the WPC team can access.

VII. Privacy and Confidentiality

Privacy

Surveys will be administered in areas where responses cannot be overheard and will be made available for participants to self-complete in the presence of the UCLA RA. If the survey is conducted over the phone, the research associate will ask the participants if this is an acceptable time to talk about their participation in the research study. Follow-up survey data may also be collected using a computer-assisted-self-interview (CASI) directly in a private setting. This provides greater privacy and has been demonstrated to elicit more accurate responses. Participants will be able to share as little or as much as they would like in the focus group interviews, allowing them control over their privacy.

Coach participants will be interviewed in a private setting. Participants will be clearly informed of this procedure during the consent process.

Amendment 05/27/20:

Qualitative interviews will be administered over the phone during COVID-19 pandemic. There will be an in-person option once we are allowed to resume in-person interviews. The research associate will make sure to be in an area where responses cannot be overheard. The research associate will ask the participants if this is an acceptable time to talk about their participation in the research study. The 19 participants currently enrolled will be able to share as little or as much as they would like in the qualitative interviews, allowing them control over their privacy.

Amendment 10/28/20:

Surveys will be administered over the phone during COVID-19 pandemic. There will be an in-person option once we are allowed to resume in-person interviews. The research assistant will make sure to be in an area where responses cannot be overheard. The RA will ask the participants if this is an acceptable time to talk about their participation in the research study. Participants will be able to share as little or as much as they would like, allowing them control over their privacy.

Confidentiality

The UCLA research team will collect data via interview, access medical record data, and maintain full study data provided by participants who have consented to participate in the research study.

Documentation of consent and HIPAA authorization will be stored in a locked file cabinet in the research office or in a secure network server with access limited to study personnel.

Data collection instruments will be labeled with a unique study identifier. For focus groups, all participants will be asked to keep what is said during the discussion between participants only. However, complete confidentiality cannot be guaranteed, and participants will be informed of this in the consent form. Furthermore, focus group interviews will be recorded. Thus, we will temporarily have voiceprints. Audio recordings will be securely stored and

transmitted. Transcription will be done promptly after each interview. Audio-recordings will be destroyed upon completion of transcription.

The file that links the study ID# with other identifying information will only be accessible to the study PI, study coordinator, and research associate and will be stored on an encrypted network drive in a password-protected file. The study database will be password-protected and only accessible to named study personnel who have completed appropriate HIPAA and human subjects research training.

With the permission of the coach study participants, we will also audio record the coach interviews. Thus, we will temporarily have voiceprints. Audio recordings will be securely stored and transmitted. Transcription will be done promptly after each interview. Audio-recordings will be destroyed upon completion of transcription.

We will be collecting sensitive information including some information that if involuntarily released could pose a risk to subjects. Therefore, we will institute an Adverse Event Protocol (found under "Other" documents of this application).

Amendment 05/27/20:

With permission from the 19 study participants, the monthly qualitative interviews will be recorded. Participants will have the opportunity to listen to, edit, and delete recording of their monthly qualitative interviews.

Amendment 10/28/20:

The WPC team will ask potential participants if they are interested in the study and if they are, they will ask potential participants for a signature in order to share their contact information (name and phone number) with the UCLA study team. The signature obtained by WPC is not meant to enroll participants in the study, but rather it is meant to allow the WPC team to share contact information with the UCLA study team. To protect participant confidentiality, these signed forms will be kept by WPC in a locked cabinet that only the WPC team can access.

The WPC team will send the research team contact information (name and phone number) for potential participants that are interested in the study. To further protect participant confidentiality, the WPC team will send a password protected spreadsheet that will be sent through our secure mednet email. We will then store the spreadsheet on our secure server. WPC will not be informed as to who decides to participate in the study.

VIII. Benefits & Risks

Benefits:

There are no potential direct benefits (physical, psychological, social or other) to study participants.

The benefits of the study are gained insight into how the Whole Person Care (WPC) Reentry Program influences health and linkages to health care. Additionally, we learn how social networks impact health behaviors for transition age youth (TAY). The insight gained form this study has the potential to guide the development of other cost-effective interventions to help youth stay out of the juvenile system.

Risks:

A breach of confidentiality is one risk of this study. We will minimize this risk by collecting information confidentially and adhering to strict protocols to ensure the safety of the data. All survey responses will be associated with a study ID number only. In order to mitigate the risk of feeling uncomfortable, we will take great care to be respectful of participants. Participation is voluntary and participants will be informed of this at study enrollment. Participants will also be told that they may drop out of the study at any time and may choose not to answer any question that makes them feel uncomfortable. Information about whether they choose to participate or not will not be shared with the detention facility, Department of Probation, the Health Agency, or anyone else. They will also be told that their decision whether or not to participate does not affect their standing with the Court or with Probation. All information provided will be kept confidential, including from parents, with the exceptions of the information that meets the standard limits to confidentiality (e.g., imminent risk of harm to self). Participants will be clearly informed of the limits to confidentiality during the consent procedure and immediately before each primary data collection activity.

Risk/Benefit Analysis:

Subjects will be told that participation is voluntary. Information about whether they choose to participate or not will not be shared with Probation or anyone else. They will be told that they may drop out of the study at any time and may choose not to answer any question that makes them feel uncomfortable. All information provided will be kept confidential, thus there is minimal risk.

The benefits of the study are gained insight into how the WPC intervention affects health and health behaviors. Furthermore, conducting this study will help us examine whether social networks are a potential mechanism by measuring whether youth receiving the intervention report healthier social networks (lower proportion of peers engaging in risky behaviors and a higher number of supportive adults) than control youth.

IX. Data & Safety Monitoring Plan

To further ensure the safety of all subjects, we (Dr. Barnert and her mentorship team) have developed a Data Safety Monitoring Board. We will convene a group of individuals outside of our research group to serve as a Safety Board that will provide study oversight. Given the nature of our survey and study design, we do not believe we need a full, rigorous and independent Data Safety and Monitoring Board. We will plan to include two consultants outside of our research group to serve as the Safety Board.

In addition, this project is part of a career development award for the PI, Dr. Barnert, and she will receive the advice of multiple mentors, such as Dr. Mitchell Wong. Dr. Wong will assist with identifying the Safety Board members, who we expect will be university faculty.

X. Payments & Cost

Each participant will receive $50 cash or gift card, based on participant preference, for each survey completed ($50 x 3 surveys= $150). If invited to participate in the focus group, participants will receive an additional $50.

For TAY who complete the baseline survey while detained, a $50 incentive will be provided for contacting the research team after their release. Payment for follow-up surveys at 3 and 9 months post-release will be provided after each survey.

For TAY exiting the juvenile justice system, participants will receive $50 after each survey completed.

No payment will be provided for the coaches who complete the study.

Subjects will not incur any financial obligations from participation in the study.

Amendment 05/27/20:

For the 19 participants currently enrolled, should they decide to participants in the new study procedures, they will receive $25 for each of the 9 monthly qualitative interviews. They will also receive an additional $50 for completing the additional follow-up survey.

Amendment 10/28/20:

Potential participants, should they decide to participate in the study, will receive $50 for each of the four surveys completed: 2 weeks post-release and then two, four, and six months after release. During the COVID-19 pandemic, to minimize in-person contact, participants will have the option of receiving these incentives through the mail or through payment apps (Venmo, Zelle, CashApp, etc.), depending on their preference. Once it is safe to do so, we will also allow for in-person delivery options.

XI. HIPAA Authorization

Amendment 10/28/20:

Previously, our study team was going to be performing chart abstractions from LA Department of Health Services records for those enrolled in the Whole Person Care initiative, but we have chosen to not move ahead with this. We will no longer be asking participants to sign a HIPAA authorization form.

XII. Recruitment Methods

For TAY exiting the adult justice system (ages 18-24), the research assistant (RA) will be approaching WPC-eligible participants while they are detained. The WPC staff will escort the RA to WPC-eligible participants as they make rounds. At this point, the RA will explain study and ask eligible participants if they are interested. If interested, consent and surveys will be done in a separate room or a location with sufficient privacy.

For TAY exiting the juvenile justice system (ages 16-19): the RA will receive a list of youth exiting the juvenile justice system who have agreed to be contacted about the study. The RA will then call youth and their families to explain the study. If interested, verbal assent and parental permission (or consent for youth 18 and older) will be obtained over the phone.

For youth exiting the juvenile justice system, youth will also receive a flyer about the study from their field probation officer during their scheduled first visit with the probation office. These visits occur within 48 hours of a youths' release. The flyer will inform youth that they may contact the research team if they are potentially interested in participation. The research team will also contact them. The flyer will also make clear that the youths' and parents' decision whether or not to participate in the study will in no way affect their standing with

probation and with the court. Probation's role with respect to the study recruitment will only be to provide names and phone numbers as well as zip code and age of potential participants to the study team. During the consent discussion, we will also request permission to ask Probation for updated phone numbers of consented study participants if, during the course of the study, we can no longer reach families with the phone numbers provided to us.

All potential participants will be reminded that their participation is voluntary, and that their participation in no way affects their standing with the Los Angeles County Jail, Probation, Sheriff's, or Health Departments.

For potential coach participants, initial contact will be made through the face-to-face meeting with the WPC staff. The research team will also receive the names and contact information of interested coaches through the WPC staff. We have made prior arrangements and have received confirmation with the WPC personnel to share the information of coaches who would be interested in participating. A research assistant or PI will call the coaches to provide more information on the study. If the coach decides not to participate, any information collected from that person will be immediately deleted.

All potential participants will be reminded that their participation is voluntary.

Amendment 05/27/20:

For the addition of monthly qualitative interviews, the research associate will contact participants that are currently enrolled and the research associate will explain new procedures and ask participants if they are interested. If they are interested, verbal consent, for the additional procedures, will be obtained.

Amendment 10/28/20:

We will be using remote recruitment and consent procedures during the COVID-19 pandemic. There will be an in-person option once we are allowed to resume in-person procedures. The Whole Person Care team will identify potential participants and will provide them with the study authorization form that will give potential participants information about the study. If they are interested, they will be required to sign the form allowing the WPC team to share their name and contact information with the team. The signature obtained by WPC is not meant to enroll participants in the study, but rather it is meant to allow the WPC team to share contact information with the UCLA study team. Once the WPC team shares this information with the UCLA study team via a password protected spreadsheet that will be sent through our secure mednet email, a research assistant will contact interested potential participants. If eligible, the RA will review the study with the interested participant and obtain verbal consent. The RA will remind the participant of the voluntary nature of the study and that participation in no way affects their standing with the Court, the Sheriff's department, or their receipt of WPC.

XIII. Permission & Assent Process for Minors and Informed Consent

Signed consent and HIPAA authorization will be obtained from participants detained in jail and exiting the adult justice system (TAY ages 18-24). For youth exiting the adult justice system, consent will be obtained in a quiet room away from others. We will ensure that participants do not feel pressure or think that their decision to participate will impact their standing with the court, the Sheriff's department or jail staff.

A request for youth verbal informed consent/assent and verbal informed parent/legal guardian permission is being requested for youth exiting the juvenile justice system. The research is minimal risk and does not involve any procedures for which written consent is normally required outside the research setting. Permission from one parent/legal guardian is sufficient. Given the nature of the study, it is not likely to provoke disagreement between the parents/legal guardians about their child's participation.

For youth who are 18 years of age or older and exiting the juvenile justice system, verbal consent will be conducted. For youth who are under the legal age of 18 years, youth verbal assent and parental permission will be obtained. The research team associate receiving verbal assent/consent and parent permission will ask youth and parents if the setting is private and will ensure participants do not feel pressure or think that their decision to participate will impact their standing with the court or with probation. We have provided a summary of the permission and assent process below:

- If youth is 18 years of age or older and exiting the juvenile justice system, only youth verbal consent is necessary for youth to participate in the surveys
- If youth is under 18 years of age and exiting the juvenile justice system, both parent permission AND youth assent are necessary for youth to participate in the survey.

A signed consent from coach participants will be obtained. Only if coaches consent, will coaches complete the interview and survey. Consent will be obtained in a private setting.

Coach consent and youth assent are independent from each other. Whether or not a youth participates is independent of whether or not a coach participates. In other words, even if a coach does not consent, a youth receiving services from that coach can participate.

Member(s) of the study staff will provide an oral explanation of the study. Individuals will be given a chance to ask questions before making a considered decision about whether or not to participate in the study.

Prospective participants/families will have the opportunity to review the script and may discuss the script with others prior to deciding whether or not to participate in the study. For verbal consents/permissions/assents conducted over the phone, the research assistant will ask the participant if they would like a copy of the consent/permission/assent prior to agreeing to participate in a form that is convenient for them (e.g. email, mail, or text message). If the participant says "yes," the research assistant will then make the consent/permission/assent available for the participant to review prior to obtaining verbal consent. A follow-up call will be scheduled to confirm receipt of consent/permission/assent script and to proceed with obtaining verbal consent/permission/assent if the participant wishes to participate in the study. For verbal consents/permissions/assents conducted in-person, the participant will have a hard-copy of the consent/permission/assent form in their native language (Spanish or English) that will be given to the potential participant. All participants will receive a copy of their respective consent document with their initial study incentive.

Amendment 05/27/20:

For those participants that are currently enrolled in the study, we are requesting verbal consent for the addendum consent that includes qualitative interviews and the additional time point for the follow-up survey. We will obtain the consent over the phone. Given the circumstances surrounding COVID-19, verbal consent will help to minimize physical

contact. All participants currently enrolled have recently exited the adult justice system (TAY ages 18-24).

Amendment 10/28/20:

Going forward, we will be using verbal consent for all adult participants exiting the justice system (TAY ages 18-24). We will obtain the consent over the phone. Aside from the study authorization form that will be provided to interested participants in jail, member(s) of the study staff will provide an oral explanation of the study. Individuals will be given a chance to ask questions before making a considered decision about whether or not to participate in the study. Given the circumstances surrounding COVID-19, verbal consent will help to minimize physical contact. Also, we have chosen to not move ahead with performing chart abstractions from LA Department of Health Services records for those enrolled in the Whole Person Care initiative, and so we will no longer require participants to sign a HIPAA Authorization form.

XIV. Cultural Considerations

The consent form and other study documents will be available in the participants' primary language. Study personnel (or qualified translators) able to discuss the participation in the patients' language will be present for the consent process. Study staff or qualified translators will discuss the study in the participants' language. An oral consent process will be used. Study personnel (or qualified translators) able to discuss the participation in the participants' language will be present for the consent process.

XV. Additional Information

I would like to address the rigorous permissions process I intend to go through with the partnering agency, the LA County Juvenile Court and Probation, before beginning any data collection. My plan is as follows: in addition to this institutional review board's approval for the study plan, I will be submitting an "order and petition for research" to the LA juvenile court. Per the protocol at the juvenile court, I will send the order for research to the presiding judge, as well as to approximately 30 other professionals at Probation and connected to the Court. I will also submit Probation's CORI (confidentiality) from for each member of the research team. Research team members in contact with the youth will obtain a live scan from Probation prior to interacting with youth. I have been in conversation with the appropriate contacts of these organizations and have obtained preliminary verbal approval. The Juvenile Court will give its final official approval through an approved petition for research and this will also serve as the approval of record for Probation. The Juvenile Court has advised me that they would only like to see the finalized study plan so I will plan to submit the Petition to the Court as soon as this institutional review board has granted approval for the proposed activities. An NIH Certificate of Confidentiality has been granted.

We will not begin study activities (i.e. recruitment/consent) until we obtain full approval from the DHS/DPH IRB and until a signed court petition for research is approved.

I would be glad to make myself available during the IRB's Board meeting to discuss the study and answer any questions. I am committed to conducting high quality, ethical research that protects the best interest of the youth and their families and that is useful for DHS. My goal is to help these highly vulnerable youth and I greatly appreciate your assistance and time.

Thank you for reviewing this application.