**Yale University**

**Consent to Participate in a Research Study and HIPAA Authorization
Adult Participants
Consent Form Version Date: 1/18/2022
IRB Study # 19-1713
Title of Study: Transitions Clinic Network: Post Incarceration Addiction Treatment, Healthcare, and Social Support (TCN PATHS)
Principal Investigator: Emily Wang
Principal Investigator Department: Medicine
Principal Investigator Phone number:** **203.737.7624** **Principal Investigator Email Address: Emily\_wang@yale.edu
Local Site Principal Investigator: Lisa Puglisi, MD**

**Local Site Principal Investigator Phone number: (203) 737-7624**

**Local Site Principal Investigator Email Address: lisa.puglisi@yale.edu**

**Funding Source and/or Sponsor: NIDA National Institute of Drug Abuse
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Project Summary**

The purpose of this study is to understand how individuals who have recently been incarcerated transition back to their communities and how they address their healthcare needs. We are also interested in learning about the effectiveness of the Transitions Clinical Network Program as an intervention to help people engage in treatment for Opioid Use Disorder.

All participants will be asked to complete six surveys about health and well-being. These surveys will be conducted over telemedicine via video, over the phone, or in-person. At the first follow-up survey, participants will be asked to provide a biospecimen (saliva or urine) for drug testing. Total duration of the study will be 12 months.

Participants completing all of the core study protocols will receive $260.

If you are interested in learning more about the study, please continue below.

**What are some general things you should know about research studies?**
You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason at any time, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or Yale University. If you are a patient with an illness, you do not have to be in the research study in order to receive health care. Your decision to participate or not will not have any effect on current or future parole board decisions, probation decisions, or sentencing decisions.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

*T/F:* Participating in this study will have an effect on future probation, parole, or sentencing decisions

**What is the purpose of this study?**
The purpose of this study is to understand how individuals who have recently been incarcerated transition back to their communities and how they address their healthcare needs. We are also interested in learning about the effectiveness of the Transitions Clinical Network Program as an intervention to help people engage in treatment for Opioid Use Disorder.

You are being asked to take part in this research study because you have had recent involvement with the criminal justice system and a history of opioid use.

**Are there any reasons you should not be in this study?**
You should not be in this study if you are:

* Planning to leave the greater \_\_\_\_\_\_\_\_\_\_\_\_\_\_area (local catchment area) after release
* Having suicidal or homicidal thoughts or behaviors
* Are experiencing psychosis or are having severe mental health symptoms
* Have a primary care provider that you have established care within the community and plan to return to their care after release
* Are currently pregnant
	+ Note: If you are pregnant at the time of enrollment, you are not eligible to participate in the study. However, if you become pregnant during the duration of the study, you can remain in the study. If you become pregnant during the study, please inform the study team.

**How many people will take part in this study?**
A total of 800 adult individuals will be recruited from five states and Puerto Rico: Durham, North Carolina; Minneapolis, MN; Ontario, NY; Bronx, NY; Bridgeport, CT; and Bayamón/Ponce, Puerto Rico.

**How long will your part in this study last?**
You will be active in this study for 12 months.

**What will happen if you take part in the study?**

**Core study activities include:**

* **Completing** six surveys about health and well-being
* **Drug testing**
* **Phone check-ins**

After the baseline survey, you will be randomly assigned to one of two study groups: the **Transitions Clinical Network (TCN) Group** or **the Standard of Care (SOC) Group.** When we say randomly assigned, we mean that a computer will determine your group assignment completely by chance, like flipping a coin.

One month after your release, you will complete an hour-long survey about substance use, health, stress, experiences of discrimination, overdose, food insecurity, and demographic information. You will be asked to provide a biospecimen (saliva or urine) for drug testing. The results of this (and future) drug test are for research purpose only and will be kept confidential. The results will not be shared with any prison personnel.

*T/F:* The results of the drug test will not be shared with anyone outside the study

Participants in the SOC group will receive what the standard of care is for everyone entering the jail with OUD. This will include access to treatment for OUD during incarceration (e.g. treatment with suboxone, methadone, or naltrexone as available) and linkage to OUD treatment in the community post-release.

Participants in the TCN Group will be assigned to the caseload of a community health worker (CHW) who can help in treatment engagement by assisting in the transition from incarceration to living in the community.

*T/F:* I get to choose if I’m referred to primary care provider with a CHW

Schedule of Core Study Activities

Participants in both groups will receive a referral to an opioid treatment program and will complete the following schedule:

|  |  |  |
| --- | --- | --- |
| Month # | Activities | Time Commitment |
| Enrollment | Survey to learn about your substance use, health, stress, experiences of discrimination, overdose, food insecurity, and demographic information | 1 hour |
| 1 | In person or over the phone survey to learn about substance use, health, stress, experiences of discrimination, overdose, food insecurity, and demographic information.  | 1 hour |
| 2 | Call to update contact information and brief check-in. | 10 - 30 minutes |
| 3 | Abbreviated survey similar to month one, including sleep follow up questions.  | 30 minutes |
| 4 | Call to update contact information and brief check-in | 10 minutes |
| 5 | Call to update contact information and brief check-in | 10 minutes |
| 6 | Same as month 1 | 1 hour |
| 7 | Call to update contact information and brief check-in | 10 minutes |
| 8 | Call to update contact information and brief check-in | 10 minutes |
| 9 | Same as month 3 | 30 minutes |
| 10 | Call to update contact information and brief check-in | 10 minutes |
| 11 | Call to update contact information and brief check-in | 10 minutes |
| 12 | Same as month 6 | 1 hour |

The study team would like to message you by text messaging, email, and social media, however you may say “no” to receiving these messages and still participate in this study.  If you say “yes”, messages may contain personal information about you and may be sent or received by the study team’s personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team.  This information may include information such as reminders and notifications to contact the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of this consent form.  After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (un-protected) messages specific to this study.

\_\_\_\_\_ Yes, I consent to the study team utilizing the following cell phone number to send communication: \_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_ Yes, I consent to the study team utilizing the following email address to send communication: \_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_ Yes, I consent to the study team utilizing the following social media accounts to send communication (include account name or handle):

Facebook:\_\_\_\_\_\_\_\_\_\_\_ Instagram: \_\_\_\_\_\_\_\_\_\_\_ Snapchat: \_\_\_\_\_\_\_\_\_\_\_

Twitter: \_\_\_\_\_\_\_\_\_\_\_ WhatsApp: \_\_\_\_\_\_\_\_\_\_\_ Other: \_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_ No, I do not consent to receive un-protected communication from the study team.

In the event you are reincarcerated during your study participation, we would like to stay in contact with you. Please check all the ways we may contact you while you are incarcerated. If you decline this communication, you can still continue with the study and it will be your responsibility to contact the study team after your release.

\_\_\_\_\_ Coordinate a research study visit (remote or in-person) with jail staff

\_\_\_\_\_ Communicate with you through mail (e.g. appointment reminders, paper surveys with prepaid return postage)

**What are the possible benefits from being in this study?**
Research is designed to benefit society by gaining new knowledge.  You will not benefit personally from being in this research study.

**What are the possible risks or discomforts involved from being in this study?**
Drug test: You may become worried or anxious when waiting for your test results. You can speak with the research assistant about your concerns and they can provide you with additional community resources. No information you provide us will be shared with jail staff, probation or parole officers. This includes the result of your drug tests.

Surveys: For the survey, you may become uncomfortable when asked to provide personal information about yourself. You may refuse to answer any of the questions asked during the study visits, and you may stop your participation in any of these activities at any time.

There is also the potential risk of loss of confidentiality—this means that there is a very small chance that other people could see the information you tell us. We do not expect this to happen because we take many steps to protect your privacy (including information about substance use or other illegal activities). However, this is a potential risk in all research studies.

Additionally, if we learn of a situation in which you are at immediate risk for self-harm or harm to others, we will take steps to assure your safety and the safety of others. There may be uncommon or previously unknown risks as well. You should report any problems to the researchers.

Naloxone: You may be offered a free naloxone kit. Naloxone is a medication that is used to reverse opioid overdoses. The most common side effect of naloxone is opioid withdrawal, since naloxone reverses the effect of opioids. Reversing an overdose can save your life. Common opioid withdrawal symptoms include aches, irritability, sweating, runny nose, diarrhea, nausea, and vomiting. Much more rare side effects have been reported from postoperative patients with pre-existing cardiovascular issues.

If you are offered a naloxone kit, a research team member will provide you with information about how to recognize signs of an overdose and how/when to use naloxone. If you are offered a naloxone kit, you do not need to accept it and this will not affect your participation in the research study. You will also be referred to other local sources where you can get naloxone in the future.

**What if we learn about new findings or information during the study?**
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

**HIPAA Authorization**

The following is a permission called a “HIPAA authorization.” It is required by the “Health Insurance Portability and Accountability Act of 1996” (known as “HIPAA”) in order for us to get information from your medical records or health insurance records to use in this research study.

In order to participate in this research study we will need your permission to access your healthcare records related to this study. If you do not want to allow this HIPAA authorization, you cannot participate in this research study. However, not signing the authorization form will not change your right to treatment, payment, enrollment or eligibility for medical services outside of this research study.

The HIPAA protections that apply to your medical records will not apply to your information when it is in the research study records. Your information in the research study records may also be shared with, used by or seen by other affiliated groups and individuals, which are outlined in the rest of this consent form. HIPAA rules do not usually apply to those people or groups. If any of these people or groups reviews your research record, they may also need to review portions of your original medical record relevant to the situation. If this research study creates medical information about you that will go into your medical record, you may not be able to see the research study information in your medical record until the entire research study is over.

You have the right to stop this HIPAA authorization at any time. However, the HIPAA authorization will not stop unless you stop it in writing. Stopping this HIPAA authorization will not stop information sharing that has already happened. You may give your written stop of this HIPAA authorization by 1) sending it directly to Principal Investigator or researcher, 2) mailing it to the department mailing address listed below, or 3) giving it to one of the researchers in this study and telling the researcher to send it to any person or group the researcher has given a copy of this HIPAA authorization.

**Mailing Address for UNC-Chapel Hill Department:** CB: 333 South Columbia Street, MacNider Hall, Room #348 / CB #7240 , Chapel Hill, NC 27599 , USA

**How will information about you be protected?**
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law, such as in situations of suspected child or elder abuse.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of the National Institutes of Health, the University of North Carolina Institutional Review Board, University of Chicago and other research partners as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

Survey: In order to contact you for the follow-up surveys at 1, 3, 6, 9, and 12 months we will collect your contact information so we can schedule the follow-up visits. We will not use your name on the survey. Instead, we will label all study documents from the surveys with a code number and not your name.

Additionally, we are taking the following steps to secure your data:

1. The computers on which the surveys are administered will be password-protected. No data will be stored locally on these devices. Data will be collected using Qualtrics which immediately sends your encrypted responses to secured servers.

2. Your answers will be matched with a study ID number, not with any identifying information about you.

3. The server and computers on which your data are stored and accessed are secure and checked regularly for viruses.

Study documents will be retained for at least six years after the study is completed. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, **your name or other personal information will not be revealed**.

If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, Yale Universitywill take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the Food and Drug Administration (FDA) for purposes such as quality control or safety.

Data will be also stored at the University of Chicago, which has been funded to manage the data collected by this and similar studies. To protect your confidentiality, information that could be used to directly identify you (e.g., your name, address, date of birth, social security or medical record number) will be stored separately from your other data and will not be shared with anyone other than the local researchers conducting this study. The National Institutes of Health require that the data collected in this study are shared with other researchers so that the data may have the greatest scientific value. For that reason, the University of Chicago will make data (without those direct identifiers) available to researchers at other institutions, who agree to use those data for scientific research only (data will not be shared for commercial or other purposes). Your data will be used for statistical analyses for research purposes, monitoring and safety, and results will be reported on groups of people only—never on individuals. Despite these steps to protect your confidentiality, we still suggest that you do not share with other people the fact that you have participated in this study.

**What is a Certificate of Confidentiality?**
This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the FDA.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

**What will happen if you are injured by this research?**
All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. Yale Universityhas not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

**What if you want to stop before your part in the study is complete?**
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

**Will you receive anything for being in this study?**
You can receive a total of $260 for completing the core study components.

* $185 total for long interviews (you will receive: $50 for baseline interview, $45 for 1 month, $45 for 6-month interview, $45 for 12-month interview)
* $40 total for brief interviews (you will receive: $20 for 3-month interview and $20 for 9-month interview);
* $35 total for monthly check ins (you will receive: $5 for each for completed check-ins at month 2, 4, 5, 8, 7, 10, and 11 months)

 *T/F:* I am required/have to complete the entire study once I sign up

If you withdraw or are withdrawn from the study, you will receive compensation for all visits completed prior to withdrawal. Any payment provided for participation in this study may be subject to applicable tax withholding obligations.

**Will it cost you anything to be in this study?**
It will not cost you anything to be in this study, but you or your insurance will be charged for standard of care treatments. This includes primary care and addiction treatment visits and blood work that your clinician orders for you that you would have had done even if you were not in this study.

**Who is sponsoring this study?**
This research is funded by a grant from the NIH National Institute of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

**What if you have questions about this study?**
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

**What if you have questions about your rights as a research participant?**
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research participant, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113, by email to IRB\_subjects@unc.edu, or letter mailed to:

UNC IRB

Second Floor CB 7097,

720 M.L.K. Jr Blvd Bldg # 385,

Chapel Hill, NC 27599

OR

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Dr. Emily Wang, MD, MAS at 203-737-7624.

**ILA Part of the Study**

If still recruiting for ILA part of the study:

[ ]  Still recruiting, read below

[ ]  No longer recruiting, skip to Sleep Measurement Portion of the Study

Participants in the TCN group could also participate in an intensive longitudinal assessment (ILA). This will require having a smart phone that can download applications. Participants enrolled in the ILA will be surveyed twice daily for 30 days using a smartphone application. Daily surveys will ask questions about CHW contact, stress, mood, opioid use, sleep, housing, and food security.

Twenty TCN participants will be selected to join the ILA portion of the study. If selected to join, you will receive $20 for downloading the smartphone application and contacting the study staff. Additionally, participants who complete at least 75% (10 out of 14) of the weekly surveys will receive a $10 weekly compensation.

*ILA Specific Risks and Protections*

For the survey, you may become uncomfortable when asked to provide personal information about yourself. You may refuse to answer any of the questions asked through the ILA prompts, and you may stop your participation in any of these activities at any time. The computers on which the surveys are administered will be password-protected. No data will be stored locally on these devices. Data will be collected using Qualtrics and the TryCycle App which immediately sends your encrypted responses to secured servers.

**Sleep Measurement Part of the Study**

Is this site participating in the sleep measurement part of the study?

[ ]  Yes, read below

[ ]  No, skip to Social Network Analysis Part of Study

Up to 220 participants will be selected to join the portion of the study that will focus on measuring your sleep and learning about where you sleep and your sleep habits. If selected to join, you will be asked to wear a small device continuously on your wrist for 2 weeks that will provide an estimate of the number of minutes spent sleeping on average. You will also be asked to complete a sleep diary and provide a photo of your sleep environment. When you return the device, sleep diary, and sleep environment photo at the end of the 2 weeks, you will receive $200.

*Sleep Measurement Specific Risks and Protections*

If you decide to wear the Actiwatch, you may find it to be uncomfortable if you’ve never worn a smart device.If you choose to be a part of the sleep measurement part of the study, all data collected form the Actiwear sleep watch will be stored on a university password protected computer.

**Social Network Analysis Part of Study**

Is this site participating in the social network analysis part of the study?

[ ]  Yes, read below
[ ]  No, skip to Participant’s Agreement

Participants in the TCN study can also participate in an assessment of their social networks (i.e., people involved in your life or are important to you). This will require completing a 30-minute survey at your first study visit and a 30-minute follow-up survey at the 6-month follow up study visit. This survey will ask questions about people involved in your life, how they support you, what they think of your substance use and substance use treatment, and how they are connected to other people involved in your life. If you consent to take part in this additional study, you will receive $35 after both the completion of the survey at the first study visit and the 6-month follow-up visit. This compensation is in addition to the compensation received for participation in other parts of the study. Your decision to be involved in this study will have no impact on your ability to participate in other parts of the TCN study.

*Social Network Analysis Specific Risks and Protections*

For the survey, you may become uncomfortable answering some survey and interview questions about yourself, people involved in your life, and your relationships with these people. You may choose to not answer questions that make you uncomfortable or stop your participation in this survey at any time. There is also a risk of loss of confidentiality. When identifying people involved in your life, we will not ask you for their full name, but only their first name and the first initial of their last name. This will be used for purposes of identifying them in the survey, but the people you name will not be contacted as part of the study. The computers on which the surveys are administered will be password-protected. No data will be stored locally on these devices.

 **Title of Study**: Transitions Clinic Network: Post Incarceration Addiction Treatment, Healthcare, and Social Support (TCN PATHS)
**Principal Investigator**: Emily Wang, MD

**Participant’s Agreement**:

I have read the information provided above.  I have asked all the questions I have at this time.  I voluntarily agree to participate in this research study.

|  |  |
| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Research Participant | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Printed Name of Research Participant |   |

|  |  |
| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Research Team Member Obtaining Consent | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Printed Name of Research Team Member Obtaining Consent |  |