Document Coversheet

Study Title: Kentucky Communities and Researchers Engaging to Halt the Opioid Epidemic (CARE2HOPE) - UH3 PHASE

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KEY INFORMATION FOR THE CARE2HOPE PHASE 2 STUDY:

We are asking you to choose whether or not to volunteer for a research study to test the effect of an intervention to reduce substance use and related harms among people in rural counties who were recently involved with the criminal justice system, meaning they were in jail or prison, out on bond, had a warrant for their arrest, arrested, on probation or parole, under pre-trial supervision, court-involved, or incarcerated at home under an electronic ankle monitoringprogram. You are being invited to take part in this research study because (1) you are age 18 or older, (2) you injected drugs or used opioids (heroin, fentanyl, or pain killers) to get high in the past 30 days (if you are incarcerated, on an ankle monitoring home incarceration program, court-involved, on pre-trial supervision, probation or parole, or enrolled in a substance use disorder treatment program, then you are eligible if you injected drugs or used opioids to get high in the 30 days before this particular involvement with the criminal justice system or substance use disorder treatment program), (3) you were in jail or prison, out on bond, had a warrant for your arrest, arrested, under pre-trial supervision, on probation or parole, court-involved, or incarcerated at home under an electronic ankle monitoring program in the past 30 days, (4) you plan to be residing in one of the counties included in the study for the next 3 months. This page gives you key information to help you decide whether to participate. We have included detailed information about this project after this page. Ask the research team questions. If you have questions later, the contact information for the person in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

This study will test the effects of an intervention to reduce substance use and related harms among people who were recently involved with the criminal-justice system, meaning they were in jail or prison, out on bond, had a warrant for their arrest, arrested, on probation or parole, under pre-trial supervision, court-involved, or incarcerated at home under an electronic ankle monitoring program. This study will compare people in a health linkage intervention with people who will only get overdose education. Participants will be assigned to one of the two groups by chance based on when their county is randomly chosen to start the project. Everyone in both groups will meet with a staff person when they join the study and again at 7 days and 3 months afterthat to answer survey questions about drug use, related behaviors, and access to services. Completion of drugtesting at each appointment is required. See below for differences between the two groups:

Overdose education group: Participants in this group will receive a 10-minute overdose education training from a research staff person when they join the study.

Health linkage intervention: Participants in this group will receive a 10-minute overdose education training from a research staff person and will receive a naloxone (Narcan) kit to carry, when they meet with the study member. Staff will also help participants develop a plan for reducing risks and accessing services. At the first visit after the survey, the staff person will meet with participants to offer HIV and HCV testing counseling, fentanyl education training and provide fentanyl test strips, other harm reduction supplies, and to connect participants with needed services. Staff will also follow up once a month for three months to help participants overcome challenges and will call the participants to check in with them. Once you complete at least two sessions, you will be invited by staff to participate in a one-time online interview to learn about your experiences with the intervention.

By doing this study, we hope to learn if providing linkage to health services, including HIV, hepatitis C, and overdose education to people who are currently or have recently been involved with the criminal justice system will reduce substance use and related harms. If you decided to take part, your participation would last about 3 months.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

All participants will receive a screening for risk behavior, overdose education, and a resource guide describing local services available. Participants in the health linkage group will also be offered HIV and HCV testing counseling, naloxone (Narcan), fentanyl education training and provide fentanyl test strips, other harm reduction supplies if needed, and help connecting with services. Participation may also benefit society because the study could inform better responses to substance use and related harms.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You should not participate in this study if you are not comfortable answering questions about sensitive topics like substance use, overdose, sexual behavior, mental health, and need for services. You should also not participate

if you are uncomfortable providing us with contact information for scheduling appointments during the study. You should also not participate if you are doing so because you feel pressured by friends, family, or probation and parole staff, or pre-trial supervision staff. If you are on probation and parole, under pre-trial supervision, or incarcerated at the time of enrollment through an ankle monitoring program with the Kentucky Department of Corrections (DOC), then note that: The DOC requires researchers to provide the DOC with the name of participants under DOC supervision and the title of the research study, if they choose to request this information. By agreeing to be in the study, you are allowing the researcher to provide your name and the study title to the DOC. The information will be sent to the DOC's Director of the Office of Research and Legislative Services in Frankfort. The researchers will not share any of your research data or confidential information with the DOC. The DOC may ask you to sign a separate consent form that verifies that you are volunteering for a study that isnot a part of the DOC.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. If you do not want to participate, it will not affect your relationship with any criminal justice, treatment, parole, or other agency. If you are on probation or parole, the researchers will not disclose any information about you or your participation in the study to the parole board or to a parole officer without your specific written authorization.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact April Young of the University of Kentucky (UK), Department of Epidemiology at 859-218-2090. If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the UK Office of Research Integrity between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You should not participate in this study if (1) you are under the age of 18, (2) you did not inject drugs or use opioids to get high in the past 30 days (if you are incarcerated, on an ankle monitoring home incarceration program, court-involved, on pre-trial supervision, probation or parole, or in a substance use disorder treatment program, then you should not participate if you had not injected drugs or used opioids to get high in the 30 days before this particular involvement with the criminal justice system or substance use disorder treatment program), (3) you were not in jail or prison, not out on bond, did not have a warrant for your arrest, not arrested, not under pre-trial supervision, not on probation or parole, not court-involved or not incarcerated at home under an electronic ankle monitoring program in the past 30 days, (4) if you cannot speak and understand English, (5) if you have ever been convicted or are currently being charged with a violent crime, (6) you plan to move out of the study counties in the next 3 months

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted in a private office at the local research office, or a place that you and the study team believe is safe and private. These visits might also take place by phone or videoconferencing. You will need to meet with a staff member up to eight times during the study. The first survey visit will take 1 ½–2 hours. The second survey visit will take 1-1 ½ hours. You will also participate in a 3-month survey visit that will take 1-1 ½ hours. If you are assigned to the intervention group, you will also have 4 health linkage visits. The first health linkage intervention visit will take about 1-1 ½ hours, and three other intervention visits will take about one hour each. The optional one-time interview for the intervention group only will take 1-1 ½ hours. The total amount of time you will be asked to volunteer for this study over the next 3 months is about 7.5-9.5 hours if you are inthe health linkage group, or 3.5-5 hours if you are not in the intervention group.

WHAT WILL YOU BE ASKED TO DO?

This study will test the effects of an intervention to reduce substance use and related harms among people who have recently been or are currently involved with the criminal justice system. This study will compare people who receive the health linkage intervention with people who will only get overdose education. Everyone will take part in 3 surveys over 3 months, the first survey will be split into two sessions. Participants will be assigned to one of the two groups by chance based on when their county is randomly chosen to start the project. People in the overdose education group and in the health linkage intervention group will be asked to do different activities. All meetings will be held in-person in a private room in the study office, or at a mutually agreed-upon location, or, if needed, by phone or by videoconferencing. Below is an explanation of the activities both groups will do, followed by a table showing differences between groups.

Survey. You will be asked questions by a research team member who will enter your responses into a computer survey. You will complete surveys either in-person, by phone, or by video conferencing for all appointments. In these follow-up surveys, the staff person will read the questions out loud to you and enter your responses. The survey asks about your personal drug use, drug-related harms (i.e., HIV, hepatitis C, and overdose), sexual behavior, and criminal justice history. Your demographic characteristics (e.g., gender, age, race) and health and social service use will also be collected. Your interview responses will be confidential.

Drug testing. At each survey visit, you will be asked to complete urine or saliva drug testing. Preliminary results of the drug test will appear within 5 minutes of urine or saliva collection. We can share the results of the test with you if you are interested.

Locator form. We will ask you to complete a Locator Form so that we can contact you for your follow-up appointments. The Locator Form asks for things like your address, email, and phone number. You may

also provide contact information for relatives and friends who will know where to find you. In gathering this information for locating you, we will only say we are trying to locate you for a "UK Health Study." We will also contact you occasionally to see if your contact information has changed.

We will not disclose the nature of the study or give any study-based information to locator sources. We may use public or private databases like LexisNexis to find updated information in order to contact you about completing the follow-up interview. In some cases, we may confidentially try to contact you through addresses or phone numbers that are or have been linked to you in some way by mail or phone.

[Both Groups] The research team will be contacting you to conduct follow up interviews. At that time, you may be living in a treatment facility, institution, jail, or prison. Participation in the study will not affect your relationship with any criminal justice, treatment, parole, or other agency that you are or may become involved with. Do you consent to being contacted in these facilities when it comes time for your follow-up?

□ Yes □ No_____Initials

We are collaborating with other UK research programs including CARE2HOPE's Gateway2Health Project, run by April Young and Hannah Cooper; and The Social Networks among Appalachian People (SNAP) study and the Kentucky Viral Hepatitis Treatment Project (KeY Treat) study, both led by Jennifer Havens, PhD, UK College of Medicine. The CARE2HOPE, SNAP, and KeY Treat programs are providing referrals to each other. If you are enrolled in this project and any of the other 3 projects and we are having difficulty reaching you for your follow up interviews, you can choose to have your contact information shared with us from these other programs if you provide permission. These programs might have more recent information available.

[Both Groups] If we are having difficulty reaching you for follow-up interviews, and you are enrolled in CARE2HOPE's Gateway2Health (G2H) project, do you give your permission for the G2H project to share your contact information?

□ Yes □ No _____Initials

[Both Groups] If we are having difficulty reaching you for follow-up interviews, and you are enrolled in the Social Networks among Appalachian People (SNAP) study, do you give your permission for the SNAP study to share your contact information?

□ Yes □ No _____Initials

[Both Groups] If we are having difficulty reaching you for follow-up interviews, and you enrolled in the Kentucky Viral Hepatitis Treatment Project (KeY Treat) study, do you give your permission for the KeY Treat study to share your contact information with us?

□ Yes □ No _____Initials

Study activity	**Health linkage intervention group**	**Overdose education group**
At the beginning - first survey (2 visits)		
You will meet with a research staff person in-person in a private room in the study office, or at a mutually agreed-upon location, or by phone, or by videoconferencing to complete the first part of a confidential, 60–90-minute	✓	✓

assessment. They will read questions aloud and will ask about your drug use, sexual risk behaviors, access to needed services, and personal goals.		
You will watch a 10-minute video on the computer that describes how to recognize and respond to an overdose. Research staff will read a pamphlet about overdose aloud if you meet by phone.	✓	✓
You will be asked for detailed contact information for follow-up visits.	✓	✓
Within 7 days, you will meet with a research staff person again in-person in a private room in the study office, or in a mutually agreed-upon location, or by phone, or by videoconferencing to complete a second part of the confidential, 60–90-minute assessment. They will read questions aloud and will ask about your drug use, sexual risk behaviors, access to needed services, and personal goals.	✓	✓
You will be asked for a urine or saliva specimen for a drug test. If needed, the staff person may bring the drug test kit to your home or to a mutually agreed-upon location.	✓	✓
[Optional. Health Linkage Group Only] You will be offered rapid (finger-prick) testing for hepatitis C and HIV. You will receive results and counseling about your results in 20 minutes. If you prefer, we can help you to test yourself using a self-test kit in the study office, or the staff person may bring the test kit to your home or a mutually agreed-upon location. You can also be referred to a local Health Department for testing.	✓	
The staff person will give you a printed resource guide about local health and social service resources or mail the guide to you	✓	✓
First Health Linkage intervention visit – within approximately 10 days after you join the study		
You will meet with a study staff person who will help you with your health and other life problems. This meeting will be in-person in a private room in the study office, or in a mutually agreed-upon location, or by phone, or by videoconferencing. The staff person will ask you about your most pressing problems and will help you set goals to support your health and meet other needs, and connect you with local services to help you carry out your goals.	✓	
The staff person will offer you naloxone (Narcan), a nasal spray that reverses opioid overdoses from heroin, pain killers, and other opioids. They will also offer education training on fentanyl test strips and provide you fentanyl test strips to reduce the risk of fentanyl-related overdose, condoms and harm reduction supplies. If needed, the staff person may bring these supplies to your home or to a mutually agreed-upon location.	✓	
The staff person will give you a printed guide about health and social services or mail the guide to you.	✓	
Second, third and fourth Health Linkage intervention visits – each within approximately 21 days after the previous intervention visit		
You will meet with a study staff person in-person in a private room in the study office, or at a mutually agreed-upon location, to see how you are doing on your goals and to help address challenges you may be encountering. If you are unable to meet with the staff member in person, they may do the visit by phone or videoconferencing.	✓	
The staff person will also offer you fentanyl test strips. We will either offer you naloxone (Narcan) or we will refer you to alocal Health Department to obtain naloxone (Narcan) or to a local pharmacythat provides Medicaid coverage for Narcan. The staff person will also offeryou condoms and other harm reduction supplies. If needed, the staff personmay bring these supplies to your home or to a mutually agreed-upon location.	✓	

A study staff person will also contact you by phone in-between the intervention sessions for a short conversation to see how you are doing on your goals and to help address challenges you may be encountering.	✓	
Once you complete at least two sessions, you will be invited by staff to participate in a one-time online interview to learn about your experiences with the intervention. This interview is optional.	✓	
Between the surveys		
Staff will contact you once (between the baseline and 3-month appointment).	✓	✓
Study staff will contact you in 2, 3 and 4 weeks after the baseline survey to remind you to refer your peers to the study.	✓	✓
Three months after the start of the study – second survey		
You will meet with a staff person one-on-one in a private space in the study office, or at a mutually agreed-upon location, to complete a confidential, 60-minute survey. They will ask you questions about your drug use, sexual risk behaviors, and access to needed services. If you are unable to meet with the staff member in person, they may do the assessment by phone or videoconferencing.	✓	✓
You will be asked for a urine or saliva specimen for a drug test. If needed, the staff person may bring the drug test kit to your home or to a mutually agreed-upon location.	✓	✓
The staff person will give you a printed guide about health and social services, or mail the guide to you.	✓	✓

People in the Health Linkage group will also be invited to take part in the following activities:

(1) **Linkage to services and goal setting**. Research staff will help you set goals and reduce your health risk by encouraging you to reflect on personal drug use, sexual relationships, and their consequences in the context of personal values and goals. Staff will not judge or pressure you if you are not ready to change some behaviors. This process is meant to meet you where you are and help move you towards your own goals. Staff will also help link you to services that you need and want. Rather than simply handing a participant a pamphlet, staff will help you contact the agency, help set up appointments, and help you get to appointments, as wanted and needed.

[Health Linkage Group Only] Do you consent to allow the research staff to contact health, social, and other service providers in the community to help you schedule appointments and/or arrange services? Research staff will only contact the services and/or agencies that they discuss with you during your assessments and that you want them to contact.

□ Yes □ No _____Initials

(2) **HIV and HCV testing and counseling**. You will be offered HIV and HCV testing by research staff in the study office. However, if you prefer, we can help you perform the test yourself using a self-test kit, or we can make a referral to a local health department.

HIV and HCV testing in local health departments is offered through UK's Kentucky Income Reinvestment Program (KIRP) with UK staff based at the health departments. The Kentucky Cabinet for Health and Family Services' Department for Public Health and UK established KIRP to improve health care delivery through education, prevention, treatment and services for persons living with HIV. Testing is offered through collaboration with harm reduction programs in local health

departments. If you provide permission, KIRP will share your test results with us.

Wherever you get tested, after your results are ready, an individual qualified to provide post-test counseling will provide the results and counseling and give you information on the next steps, including treatment.

HIV testing and counseling

(1) Testing by research staff. HIV testing by research staff will require a finger stick and waiting 2 minutes for the results. If you choose to be tested for HIV, you will be informed of the result. If you test positive on the finger stick test, you will be offered a second test to confirm the result. The second test is also done by finger stick and the results will appear in 15 minutes. When your results are given, an individual qualified to provide post-test counseling will provide the results and counseling and give you information on how and where to seek treatment. Your participation in HIV testing is completely voluntary and will not affect your participation in the research study.

If you test positive on both HIV tests, we will need to report the infection to the state health department. This requires us completing a form that asks for your name and contact information; information on your age, race and gender; risk behavior; HIV treatment history; and HIV testing history. We will mail this form to the state health department and then a disease intervention specialist from the health department will contact you by phone, mail, or in person to review your information and ask you about your contacts (drug partners, sex partners). The specialist will then contact these partners to encourage them to seek testing, but they will not tell your partners any information about you or that you have tested positive.

(2) Self-testing. If you prefer, we can help you to do the test yourself using a self- test kit at the study office, or a staff member will bring the test kit to your home or a mutually agreed -upon location. An HIV self-test will require a mouth swab and waiting 20 minutes for the results. If you test positive on the mouth swab test, we will refer you to a local Health Department for a confirmatory test. If you test positive on the health department's confirmatory HIV test, they will report your results to the state health department. Your participation in HIV testing is completely voluntary and will not affect your participation in the research study.

(3) Referral to health department. If you prefer, we will refer you to a local Health Department for HIV testing offered by UK's Kentucky Income Reinvestment Program (KIRP) with UK staff based at the health departments.

[Health Linkage Group Only]

Do you consent to be tested for HIV?

□ Yes □ No _____Initials

If yes, how would you like to be tested (choose one option)?

□ Testing by research staff _____Initials

□ Testing yourself using a self-test kit_____Initials

□ Testing at a local health department through UK's Kentucky Income Reinvestment Program ____Initials
If you prefer to be tested at a local health department through UK's Kentucky Income Reinvestment Program (KIRP), do you give your permission for KIRP to share your HIV test results with us?

□ Yes □ No _____Initials

Hepatitis C testing and counseling

(1) Testing by research staff. Testing for hepatitis C by research staff will require a finger stick and waiting 20 minutes for the results. You will receive the outcome of the test regardless of the result and receive post-test counseling, including information on how and where to seek further testing.

(2) Self-testing. If you prefer, we can help you to do the test yourself using a self-test kit at the study office, or a staff member will bring the test kit to your home or a mutually agreed-upon location. A hepatitis C self-test will require a finger stick. We will mail the blood spot to the lab for testing. We will access the test results online and share them with you. If you test positive on the hepatitis C self-test, we will refer you to a local Health Department for a confirmatory test.

(3) Referral to health department. If you prefer, we will refer you to a local Health Department for HCV testing offered by UK's Kentucky Income Reinvestment Program (KIRP) with UK staff based at the health departments.

[Health Linkage Group Only]

Do you consent to be tested for HCV?

□ Yes □ No _____Initials

If yes, how would you like to be tested (choose one option)?

□ Testing by research staff _____Initials

□ Testing yourself using a self-test kit_____Initials

□ Testing at a local health department through UK's Kentucky Income Reinvestment Program____Initials
If you prefer to be tested at a local health department through UK's Kentucky Income Reinvestment Program (KIRP), do you give your permission for KIRP to share your HCV test results with us?

□ Yes □ No _____Initials

HIV and HCV testing are also offered through CARE2HOPE's Gateway2Health Project, The Social Networks among Appalachian People (SNAP) study and the Kentucky Viral Hepatitis Treatment Project (KeY Treat) study. If you are enrolled in this project and any of the other 3 projects and you have been tested for HCV and HIV by any of the other 3 projects in the past 6 months, you can choose to have your test results shared with us if you provide permission.

[Health Linkage Group Only] If you have been tested for HIV/HCV in the past six months through the CARE2HOPE Gateway2Health project, do you give your permission for CARE2HOPE project to share your test results with us?
□ Yes □ No □ Not Applicable _____Initials

[Health Linkage Group Only] If you have been tested for HIV/HCV in the past six months through the SNAP project, do you give your permission for SNAP study to share your test results with us?
□ Yes □ No □ Not Applicable _____Initials

[Health Linkage Group Only] If you have been tested for HIV/HCV in the past six months through the KeY Treat project, do you give your permission for KeY Treat study to share your test results with us? □ Yes □ No □ Not Applicable _____Initials

(3) **Naloxone**. People in the health linkage group will be offered a naloxone (Narcan) kit in their first appointment with research staff. Research staff will show a short video that shows how to use the naloxone kit. Research staff will also explain that if you witness an overdose, you should always first call 911 before using the naloxone. The staff person will answer questions you have and will provide you with a handout explaining how to use it.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Taking part in this study may present some risks, though we believe they are minimal. Some of the survey questions are sensitive and personal. Often, talking about the substance use and related harms like overdose might be distressing. You do not have to answer any questions that you do not want to answer, and you can stop answering questions or quit at any time. If you skip questions or end your participation early, you will still receive full compensation for the interview. The study staff are taking every precaution so that the information you provide is not available to anyone except study staff.

The surveys will ask you about your substance use and you will be asked to complete a urine or saliva drug screening. If this information or your participation in the study were to become public or known to other people, these disclosures might cause embarrassment and could hurt your standing with people in the community who have a negative attitude toward people who use drugs, toward research, or toward you because you are talking to study staff about private information. This information could affect your ability to get or keep a job with people or organizations who do not want to employ people who use drugs.

We will contact you using the information you provided on the Locator Form to remind you of follow-up appointments; we will only say we are trying to locate you for a "Health Study" and will not tell them about the topic of the study. However, individuals other than you who answer the phone or receive these communications may become suspicious and could cause you physical or psychological or emotional problems.

For people in the Health Linkage intervention, there may also be social risk such as impact on employment, insurance, and freedom to travel to other countries if you learn you have HIV or hepatitis C. Often, people become emotionally distressed if they find out they have HIV or hepatitis C. More rarely, people experience physical or psychological or emotional problems such as anxiety or depression in

response to learning they have HIV or hepatitis C. Depending on where you are tested, a Department of Health staff or a member of the research staff will provide post-test counseling and can make referrals for community services.

For people in the Health Linkage intervention, taking part in goal setting and linkage to services with staff may also present some risks. There may also physical or psychological or emotional problems such as anxiety or depression if you are unable to meet your goals or if you encounter barriers to services or have negative experiences with services in the community. Staff will not judge or pressure you if you do not meet your goals and will help you to revise them or address reasons why they were not met. Staff will also try to help you through barriers you run into when trying to access services but will not be able to address them all.

Participants in the health linkage group will receive the nasal spray naloxone (Narcan) to carry with them in case they encounter someone who has an opioid overdose or in case they have an opioid overdose and a friend can use the naloxone to respond. Research staff will show a short video that shows how to use the naloxone kit and perform rescue breathing. Research staff will answer questions and will provide you with a handout explaining how to use it and possible side effects. Naloxone temporarily reverses the effects of opioid overdose and is not a substitute for emergency medical care. If you witness an overdose, you should call 911.

Naloxone can cause side effects, including but not limited to sudden opioid withdrawal symptoms. The signs and symptoms of an opioid emergency can return after the nasal spray is given. If this happens, another dose of naloxone should be given, and the person should be watched until emergency help arrives. Naloxone only works on opioid-related overdoses and has no effect on people who are not using opioids. Witnessing an overdose can cause physical, psychological, or emotional problems such as anxiety or depression. If you administer naloxone, you may experience additional physical, psychological, or emotional problems because the naloxone effects may wear off and overdose symptoms could return, the person may experience side effects, and/or the person may become irritable or violent.

Kentucky's Good Samaritan law is supposed to protect you from being charged or prosecuted for drug or paraphernalia possession if you call 911 because you witness an overdose and stay with that person. But in rare cases, law enforcement may arrest you if you have warrants for another crime or if they have a search warrant or if they are unfamiliar with the law. If people find out that you have naloxone, it might cause embarrassment and could hurt your standing with people in the community who have a negative attitude toward people who use drugs and/or toward naloxone.

In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from taking part in this study. However, all participants will receive screening for risk behavior, overdose education, and a resource guide describing local services. Some people have experienced benefits of receiving screening for risk behavior when they become more aware of their risks and may change their behavior. Some people have experienced benefits of receiving overdose education when they encounter someone who overdoses and are able to help, or when they have shared the information with friends who successfully respond to their overdose. Finally, some people experience benefits of having information about local health and social resources because it can help them access care and services they need if they contact the listed agencies.

Participants in the Health Linkage intervention group will also receive the overdose-reversing nasal spray naloxone (Narcan) to carry with them in case they encounter someone who overdoses or in case they overdose and a friend can use it to respond. Participants in the Health Linkage intervention group will also receive fentanyl education training and fentanyl test trips to reduce the risk of fentanyl-related overdose, and other harm reduction supplies like condoms which can help prevent them from getting sexually transmitted infections when used consistently and correctly. Participants in the Health Linkage intervention group will also receive help connecting with services and will be offered HIV and hepatitis C

testing and counseling. We will we provide rapid (finger-prick) testing for hepatitis C and HIV. Alternatively, if participants prefer, they can opt to do either of the following:

(1) We can provide self-testing kits and counseling for HIV and hepatitis C at the study office or at the participants' homes or other mutually agreed-upon locations.

(2) We can also provide a referral to a local Health Department.

Participation in the study might also benefit society because the study will provide important information that could help create better community responses to substance use and related harms.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

There is no cost to you for participating in the study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will ask for your social security number on the locator form so that it can help us look you up in online databases if we are unable to contact you for your follow-up appointments using the contact information you provided. We also use it to search records databases to learn if a participant is deceased. Providing your social security number is optional; you can refuse to provide it and it will not affect your ability to participate in the study or to get paid for participation in the study.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. Your name will be kept separate from the information you give, and these two things will be stored in different places under lock and key. Also, all electronic data will be password protected and accessible only to the researchers on this study. Only a research identification number will be placed on your research records and audio recordings. Your name, address, and research number will be placed in one location that will be locked at all times except when they are being used by selected research staff. None of this information will be made known to anyone but select research staff.

You should know that in some cases we may have to show your information to other people.

For example, the law may require us to share your information with authorities, if you report information about a child being abused; or if you pose a danger to yourself or someone else.

To make sure the study is conducted properly, officials of the National Institutes of Health and/or the University of Kentucky may look at or copy pertinent portions of records that identify you.

Certificates of Confidentiality (CoC):

To help us protection your privacy, this research has a Certificate of Confidentiality. The researchers can use this Certificate to refuse to disclose information that may identify you to anyone not connected with this study, or in any legal proceedings. The exceptions to this rule are release of information:

- you have requested us to provide, for instance, to your insurance company or doctor;
- to the sponsor (e.g., National Institutes of Health) or agency auditing the research (e.g., Food and Drug Administration);
- about child or elder abuse, neglect, or harm to yourself or others; and

This policy does not prevent you from releasing information about your own participation in this study.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study. If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed. The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- you threaten or pose a risk to safety of study staff,
- we learn that you are participating in the study because someone pressured you to do so,
- we find that you have already enrolled in the study previously (i.e., enrolled twice),
- we learn that you moved to a county that is not actively enrolling participants within 21 days of your enrollment to the study,
- we learn that you are under the age of 18, are being charged with or have ever been convicted of a violent crime, are transferred to prison, and/or have been incarcerated for more than one year
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the research staff person know if you are in another research study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call April Young at 859-218-2090 immediately.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study. Medical costs related to your care and treatment because of study-related harm will be your responsibility.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will receive $85 over the course of 3 months for taking part in this study. In addition, you may refer people to this study, and for each person up to three who is eligible, you will receive $10 (i.e., a total of $30). You will receive $30 for the optional one-time online interview (health linkage group only). The total amount you could receive is up to $145. With a few exceptions, study payments are considered taxable income reportable to the Internal Review Service (IRS). A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

The amounts per activity and methods of payment are listed in the table below.

Study activity	Amount	Method of Payment
In-person survey (Baseline 1)	$25	Reloadable debit card
In person survey (Baseline 2) –within 10 days of completing first survey.	$10	Reloadable debit card
Both groups: urine or saliva drug screening and update/verify locator form Health Linkage intervention group only: rapid (finger prick) test for HIV and hepatitis C by staff; or rapid self-test for HIV (mouth swab) and hepatitis C (finger prick) testing is chosen **(optional)**	$15	
In-person survey with research staff within 3 months of completing first survey	$25	Reloadable debit card
Update and/or verify locator between baseline and 3-month appointment	$10	Reloadable debit card
Health linkage intervention group only: one-time online interview **(optional)**	$30	Reloadable debit card
Referral fees for up to 3 persons, $10 per person **(optional)**	Up to $30	Reloadable debit card
TOTAL	$85-145	

WHAT IF INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information. We will provide you with individual research results.

The tests for HIV and hepatitis C are not perfect. The sensitivity of the rapid HIV (finger prick) test (chances that I am HIV positive given that the test is positive) is 99.6%. The specificity of the test (chances that I am HIV negative given that the test is negative) is 99.3%. If you test positive for HIV on the first test, we will re-test you with a second confirmatory test. The HIV confirmatory test has a 99.8% sensitivity and 99.8% specificity. The sensitivity and specificity of the hepatitis C test is 98.1% and 99.6%. I understand that even if I do not agree to be tested, I can still participate in the research study.

If you choose self-testing, you will receive an oral swab HIV test and finger prick test for hepatitis C. The sensitivity of the HIV oral swab test (chances that I am HIV positive given that the test is positive) is 91.7%. The specificity of the test (chances that I am HIV negative given that the test is negative) is 99.9%. If you test positive for HIV on self-test kit, we will refer you to a local Department of Health for confirmatory

HIV testing that has very high sensitivity and specificity. The sensitivity and specificity of the hepatitis C self-test is above 99%. I understand that even if I do not agree to be tested, I can still participate in the research study.

There is a slight possibility that during a research project, an investigator could discover something that could affect the health of you or your family. If this occurs, the finding will be reviewed by a special committee to determine if it is in your best interest to contact you.

[Both Groups] Do you give permission for us to contact you about research results or incidental findings that are determined to be important to you/your family's health? (Incidental findings are unforeseen findings discovered during the course of the research that may affect you or your family's health).

□ Yes □ No _____Initials

You may also withdraw your consent to be contacted with information about research results or incidental findings by sending a written request to April Young at the University of Kentucky College of Public Health at 111 Washington Avenue, Lexington, Kentucky 40536.

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

The research staff would like to contact you in the future with information about participating in more studies. If so, it will be limited to no more than four times per year.

[Both Groups] Do you give your permission to be contacted in the future by April Young, Hannah Cooper, or their staff members regarding your willingness to participate in future research studies?

□ Yes □ No _____ Initials

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 960 people to do so.

The National Institutes of Health, Centers for Disease Control and Prevention, Appalachian Regional Commission, and Substance Abuse and Mental Health Services Administration are providing financial support and/or material for this study.

The information that you are providing will no longer belong to you. The research may lead to new clinical or educational knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives if this occurs.

A description of this clinical trial will be available on ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WILL YOUR INFORMATION BE USED FOR FUTURE RESEARCH?

Identifiable information (e.g., your name or date of birth) with the exception of ZIP code, city name, and county name will be removed from the information or samples collected in this study. By consenting to this study, you agree to allow researchers on this study to share information, including ZIP code, city name, and county name, with other researchers, including the University of Washington who serves as the Data Coordinating Center for this project, without your additional informed consent. We may also share these data in aggregate with members of the community coalition who will be trained in research

privacy and confidentiality and who will be deciding what services to add to your community to address local drug-related harms. If we share other data with researchers or the community coalitions in the future, it will not have information that can identify you unless you give your consent/authorization or the UK Institutional Review Board (IRB) approves the research. The IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human subjects, to make sure the study complies with these before approval of a research study is issued.

STORING AND SHARING YOUR INFORMATION FOR FUTURE USE:

We would like to store, use, and share your survey data and test results for future research. Having information from many people helps researchers find trends and discover better ways to diagnose, prevent, and treat many conditions. Researchers can use the stored information to learn more about substance use, related risk factors, and associated harms, or to research other scientific questions.

WHERE WILL INFORMATION BE STORED AND FOR HOW LONG?

The information will be stored at the University of Kentucky Center on Drug and Alcohol Research indefinitely, and at the Emory University Rollins School of Public Health for up to 5 years beyond the end of the study.

ARE THERE RISKS FROM ALLOWING YOUR INFORMATION TO BE STORED FOR FUTURE RESEARCH?

There is a risk that someone could get access to the stored information or samples. In spite of the security measures and safeguards we will use, we cannot guarantee that your identity will never become known. There may be risks that at this time are unknown. As technology advances, there may be new ways of linking information back to you that we cannot foresee now.

HOW WILL YOUR PRIVACY AND CONFIDENTIALITY BE PROTECTED?

We will take careful steps to keep your information confidential. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private. We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. Your name will be kept separate from the information you give, and these two things will be stored in different places under lock and key. Also, all electronic data will be password protected and accessible only to the researchers on this study.

Only a research identification number will be placed on your research records. Your name, address, and research number will be placed in one location that will be locked at all times except when they are being used by selected research staff. Thus, none of this information will be made known to anyone but select research staff.

The staff follow procedures to protect your identity to the extent allowed by law. In very unusual cases, staff may be required to release your identifiable medical and research information in response to an order from a court of law. You are protected by a Federal Certificate of Confidentiality which prohibit the use of any of your data in any criminal or other legal proceeding. We have obtained a certificate of confidentiality from the Department of Health and Human Services (DHHS). This Certificate protects investigators from being forced to release any identifying research data in which you are identified, even under a court order or a subpoena.

This protection, however, is not absolute. If you reveal any information about a child being abused, exploited, or neglected, the researchers may make a report to the Kentucky Department of Community Based Services. Should a report have to be made, the child's name, address, and parents' names will have to be given to the interviewer who will then report this information to the Department of Community Based Services. Researchers may also provide information to the proper individuals and organizations if intent to harm others is revealed during the course of the study.

In addition, officials of the National Institutes of Health and the University of Kentucky may look at or copy pertinent portions of records that identify you.

HOW WILL WE SHARE YOUR INFORMATION WITH OTHER RESEARCHERS?

The researchers requesting access to information must submit a written request describing their plans to use and protect the data. The researchers who receive your information will sign an agreement to usethe data responsibly.

Before sharing your information, we will remove identifiers such as your name or date of birth. Your de-identified information may be shared with other University of Kentucky (UK) researchers and researchers outside of UK, without your additional informed consent. We will use a database to track information shared without releasing your identity.

WHAT IF YOU CHANGE YOUR MIND AND WANT TO WITHDRAW YOUR INFORMATION?

You may withdraw your permission to allow your information or samples to be used for future research. To do so, you must send a written withdraw request to April Young at the University of Kentucky College of Public Health at 111 Washington Avenue, Lexington, Kentucky 40536.

We will destroy any remaining information and samples that have been stored. In addition, it may be possible to destroy the code that links you with your information and specimen samples. However, we cannot withdraw the information and samples that have already been used.

WILL YOU RECEIVE ANY COMMERCIAL PROFIT FROM FUTURE RESEARCH DISCOVERIES?

The information and samples that you provide will no longer belong to you. The research may lead to new medical knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives should this occur.

INFORMED CONSENT SIGNATURES

For participants under DOC supervision: If you are on probation and parole, under pre-trial supervision, or incarcerated through an ankle monitoring program with the Kentucky Department of Corrections (DOC) at the time of enrollment into this study, then note that: The DOC requires researchers to provide the DOC with the name of participants under DOC supervision and the title of the research study, if they choose to request this information. By agreeing to be in the study, you are allowing the researcher to provide your name and the study title to the DOC. The information will be sent to the DOC's Director of the Office of Research and Legislative Services in Frankfort. The researchers will not share any of your research data or confidential information with the DOC. The DOC may ask you to sign a separate consent form that verifies that you are volunteering for a study that is not a part of the DOC.

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**

You will receive a copy of this consent form.

_____	_____
Signature of research subject	Date
_____	
Printed name of research subject	
_____	_____
Printed name of [authorized] person obtaining informed consent	Date

Verbal Consent

If the consent form is reviewed with an individual by phone or by videoconferencing, check the applicable statement.

□ **The individual agrees to participate in the study and provides verbal consent.**

_____
Name of research subject

_____
Printed name of [authorized] person obtaining informed consent and documenting permissions on behalf of the participant

_____
Date

□ **The individual is not interested and does not agree to participate in the study.**