Document Coversheet

Study Title: Culturally AdapTed Harm Reduction Intervention: Community Engaged InterVention for Black Adults That MisusE Opioids and Stimulants

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University of Kentucky
Consent to Participate in a Research Study
KEY INFORMATION
FOR PARTICIPANTS IN THE THRIVE STUDY (Aim 2)

We are asking you to choose whether to volunteer for a research study that is conducted both by the University and Kentucky and the University of Cincinnati that will develop (in Aim 1) and test (in Aim 2) a culturally adapted intervention for use of harm reduction resources among Black adults who use opioids and/or stimulants. You are currently volunteering to participate in Aim 2 of the study to test an opioid overdose harm reduction intervention that was adapted by the investigators and a group of up to 8 individuals in Aim 1. Harm reduction is an approach that provides resources to reduce the potential harms and health consequences of drug use. Ultimately, our goal is to develop ways to improve access, motivation, and confidence using Narcan for opioid overdose reversal and using fentanyl test strips (FTS) to check drug supplies for the presence of fentanyl before using. This page gives you key information to help you decide whether to participate. We have included detailed information about the study after this page. Please feel free to ask the research team any questions. If you have questions later, the contact information for the research investigators in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?
By participating in this study, we will learn more about the unique barriers, challenges, and strengths regarding utilization of harm reduction resources in Black communities. In Aim 2 of this study, we will test the initial effectiveness and feasibility of an opioid overdose harm reduction intervention that was developed in Aim 1 of this study. We are asking you to participate in a one session group intervention with a survey before and after, followed by a one-time qualitative focus group in Aim 2.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?
By volunteering to participate in this study, you may help to reduce the negative impacts of the opioid epidemic for Black American individuals, families and communities in Kentucky and Ohio. You may feel empowered by your involvement in research that could improve treatment and access to culturally relevant resources and have a positive impact on community policy and practice. The THRIVE study will generate important information that can serve as the foundation to culturally-tailor treatment approaches and improve treatment outcomes among Black Americans. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?
To the best of our knowledge, answering questions and participating in the intervention and qualitative focus group in Aim 2 have no more risk of harm than you would experience in everyday life. However, if answering questions in the qualitative focus group or on the survey cause you to feel emotional distress, you may choose not to answer questions, or you may choose to stop participating. You can also choose not to participate in survey questions. If you do not want to be in the study, there are no other choices except to not take part in the study. For a complete description of risks, refer to the Detailed Consent. Further, if you do not want to be audio-recorded, you may choose to not participate in the study. If you are not willing to be audio-recorded, there is no alternative option, thus, you will be asked to withdraw from the study.

DO YOU HAVE TO TAKE PART IN THE STUDY?
If you decide to take part in the study, it should be because you want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?
The people in charge of the study are Brittany Miller-Roenigk, PhD and Danelle Stevens-Watkins, PhD, of the University of Kentucky's Department Educational, Counseling and School Psychology, and Paris Wheeler, PhD, of the University of Cincinnati's Department of Psychology. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, you can contact the study directors at: brittany.miller-roenigk@uky.edu or paris.wheeler@uc.edu; (513) 556-1518.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) during business hours (8am-5pm EST), Monday-Friday at (859) 257-9428 or toll free at 1-866-400-9428. Alternatively, contact staff at the University of Cincinnati Human Research Protection Program at 513-558-5259 during business hours (8am-5pm EST).

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?
You would be excluded from voluntarily participating in this study in Aim 2 of this study if you do not self-identify as Black or African American, are not willing to be audio-recorded during the qualitative focus group, you do not speak English, you are not at least 18 years of age, you are older than 65 years of age, or if you have not used an opioid and/or a stimulant drug not prescribed to you or in a way that was not prescribed (e.g., more than prescribed) in the past six months. Further, you will not be eligible to participate in Aim 2, if you completed Aim 1 of the study.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?
For Aim 2 of the study, focus groups will be conducted at one of two possible locations depending on your city of residence: a private room at the LCCC in Louisville, KY, a private room in Clifton Court Hall at the University of Cincinnati in Cincinnati, OH, or a private room at the Urban Minority Alcoholism and Drug Abuse Outreach Program (UMADAOP) in Cincinnati, OH. You will need to come once for Aim 2, and this study visit will take about 90 to 120 minutes. The total amount of time you will be asked to volunteer for this study is about 90 to 120 minutes.

WHAT WILL YOU BE ASKED TO DO?
Aim 2 Intervention, Survey, and Focus Group: You will meet in person with a group of approximately 8-10 individuals, though potentially less, plus up to four study team members for about 90 to 120 minutes. You will complete a brief survey prior to participating in a harm reduction intervention as a group. You will then complete another brief survey after the intervention to assess your perceptions about harm reduction. After the post-intervention survey, the group will participate in a qualitative focus group to be asked for feedback on the quality and overall impressions of the intervention adaptations; feasibility of the intervention; the extent to which you believe the intervention will be helpful in improving harm reduction practices among Black individuals; additional changes you recommend; perceived knowledge and motivations related to topics of the intervention; and any additional barriers you expect with implementation of the adapted intervention. These responses will be audio-recorded with HIPAA-compliant Zoom software with your permission. Audio-files will be transcribed by Rev, a professional and confidential transcription service. Audio-files will be stored on a password protected, encrypted, HIPAA compliant University OneDrive and will be kept for 90-days. Audio-files will be transcribed within 90 days of the focus group and audio files will be destroyed or erased using a data overwriting software per University policy. Transcriptions will be de-identified and will not have your name or identifying information.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?
Some of the questions that you will be asked are sensitive and personal, including drug use, which may be uncomfortable. You may also feel uncomfortable in a group setting. We stress the importance of keeping the identities and discussions talked about in these sessions confidential and to not share outside of the research context. You do not have to answer any questions that you do not want to answer. You can stop answering questions or quit participating at any time, and this will not affect your participation in services in any way. 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, some people have experienced feelings of empowerment by their involvement in research that could have a positive impact on community health policy and practice to address the opioid epidemic. Participants may also benefit from the interaction with THRIVE study staff, as they will learn about resources in their communities. If you take part in this study, information learned may help others.

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 are no costs to you for participating in the THRIVE study. However, if you choose to text or use a cell phone to contact our study staff you may incur fees from your cell phone carrier. Further, if you use public transportation

or ride share to get to our study site, you may incur the expense of those services. Please email us at thrivestudy@uky.edu if you would like to discuss potential assistance with transportation costs.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from this study, we will write about the combined information. 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. All materials will be used for research purposes only and will remain strictly confidential. Individual survey data, transcripts, will only be identified by a participant's unique ID number. The master list of names and study ID numbers will be stored in a separate location from the research forms. Notably, audio-recordings will be sent to professional and confidential transcription service (Rev) for transcribing. While they have confidentiality policies to prevent unauthorized use, we are unable to guarantee confidentiality and privacy through use of third-party applications. As a safeguard, if you do not want your name on the recording, do not state your name during the focus group session. After transcription, transcripts will be de-identified for storage and use to the research team. Given the focus group nature of the study, we are unable to guarantee confidentiality of information shared in the focus group. However, it is important to not share information learned from others in the focus group with anyone outside of the research context. If you do not feel comfortable participating in a focus group, you may withdraw from the study. The participant database will be password protected and stored on a computer/server that is also password protected within a locked office. All data will be kept in locked file cabinets at the LCCC or in a private office at the University of Cincinnati. Only this study's research staff will have access to this confidential information. Identifying research data will **not** be shared with any other individual or community-based organization. All study records will be maintained for six years after completion of study. Thereafter, records that contain your identifying information will be destroyed or erased using data overwriting software per University policy and sponsor directives. Information that could identify you will be removed from the study data. After removal, the study data could be used for future research studies. The study data could also be given to another researcher for future research studies. This may be done without getting additional permission from you.

- You should know that in some cases we may have to show your information to other people in the case of reporting child abuse or elder abuse. 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 help us protect 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
- About you if it involves a reportable disease.

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

Because this research is sponsored by the University of Kentucky Center for Clinical and Translational Science (CCTS) and the University of Cincinnati Center for Clinical and Translational Science and Training (CCTST) under funds supported by the National Institute of Health (NIH), staff from these agencies may review records that identify you. Officials from University of Kentucky or the University of Cincinnati may also look at or copy portion of records that identify you to ensure your protection in this research project. We will make every effort to safeguard your data. Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of the University of Kentucky or the University of Cincinnati. When results of this study are published, your name will not be used. This policy does not prevent you from releasing information about your own participation in this study.

Aim 2 is a clinical trial, where investigators are pilot testing the feasibility of an adapted harm reduction intervention. Thus, aggregate demographic information will be reported in ClinicalTrials.gov. No identifiable information or individual research data will be shared.

Participants in Louisville will be compensated via the UK loadable rewards card program. To load cards, participant ID numbers will be shared with University of Kentucky Accounts Payable to load the visa rewards cards through US Bank. No identifiable information will be shared externally due to CoC protections. For business protocol, first and last names will be stored internally within the PIs department at the University of Kentucky for card record keeping. No research data will be shared internally or externally for this process. Cards will be loaded within 24-hours, typically within the same business day of your participation.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?
You can choose to leave Aim 2 of this 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,
- 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 Aim 2 of this study if you are currently involved in another research study, unless you participated in Aim 1 of the study. It is important to let the investigator/your doctor know if you are in another research study. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this 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 participating in this study, you should call Paris Wheeler, PhD at (513) 556-1518 or Brittany Miller-Roenigk at brittany.miller-roenigk@uky.edu immediately.

It is important for you to understand that neither the University of Kentucky nor the University of Cincinnati 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 and the University of Cincinnati 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 a $50 gift card upon completion of your study visit in Aim 2. You will also receive Narcan and Fentanyl Test Strips (FTS) at the study visit.

Participants in Louisville will be compensated via the UK loadable rewards card program. To load cards, participant ID numbers will be shared with University of Kentucky Accounts Payable to load the visa rewards cards through US Bank. No identifiable information will be shared externally due to CoC protections. For business protocol, first and last names will be stored internally within the PIs department at the University of Kentucky for card record keeping. No research data will be shared internally or externally for this process. Cards will be loaded within 24-hours, typically within the same business day of your participation.

WHAT IF NEW 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 Aim 2 of 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?
If requested, at the completion of the study, we will provide you with individual research results of the completed pre-and post-intervention surveys. This information will include any changes you report from before the

intervention in Aim 2 to afterwards. If you want this information, please request it from request Paris Wheeler, PhD, paris.wheeler@uc.edu (513) 556-1518 or Brittany Miller-Roenigk, PhD brittany.miller-roenigk@uky.edu and we will verbally give you this data.

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). For example, do you give permission for us to share with you unexpected or expected findings related to overdose risk or harm reduction? Communications will be made by contacting the participant's contact number.

☐ 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 Paris Wheeler, PhD, paris.wheeler@uc.edu (513) 556-1518 or Brittany Miller-Roenigk, PhD brittany.miller-roenigk@uky.edu.

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 additional studies. If so, it will be limited to two times per year.

Do you give your permission to be contacted in the future by Paris Wheeler, PhD or Brittany Miller-Roenigk, PhD or their staff 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 Aim 2 of this study, you will be one of about 48-60 people to do so across all focus groups. Prior to Aim 2, up to 8 additional individuals participated in the focus groups for Aim 1 of the study to adapt a harm reduction intervention. The National Institutes of Health, the University of Kentucky CCTS, and the University of Cincinnati CCTST are providing financial support for this study.

WILL YOUR INFORMATION (OR SPECIMEN SAMPLES) BE USED FOR FUTURE RESEARCH?
All identifiable information (e.g., your name) will be removed from the information collected in this study. This means that your identity will not be kept. After identifiers have been removed, the information may be used for future research or shared with other researchers without your additional informed consent. Once you give your permission to have your de-identified information or samples stored, they will be available indefinitely.

WHAT IF YOU CHANGE YOUR MIND AND WANT TO WITHDRAW YOUR INFORMATION?
You may withdraw your permission to allow your information to be used for future research. To do so, you must send a written withdraw request to either Brittany Miller-Roenigk, PhD, 251C Scott St., Lexington, KY 40506; or Paris Wheeler, PhD, Department of Psychology, 2800 Clifton Ave Room 3230, Cincinnati, OH 45221.

Data collected from your participation in the study will remain in the study database and may not be removed, however, we will indicate that your information is not to be used for future research. We will be unable to withdraw the information that have already been used.

WILL YOU RECEIVE ANY COMMERCIAL PROFIT FROM FUTURE RESEARCH DISCOVERIES?
The information that you provide in this study 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

This consent includes the following:

- Key Information Page
- Detailed Consent

You will receive a copy of this consent form after it has been signed.

Signature of research subject	**Date**
Printed name of research subject	
Printed name of person obtaining informed consent	Date

University of Cincinnati
Consent to Participate in Human Research
KEY INFORMATION
FOR PARTICIPANTS IN THE THRIVE STUDY (Aim 2)

Participant Name:_____

Date of Birth:_____

We are asking you to choose whether to volunteer for a research study that is conducted both by the University and Kentucky and the University of Cincinnati that will develop (in Aim 1) and test (in Aim 2) a culturally adapted intervention for use of harm reduction resources among Black adults who use opioids and/or stimulants. You are currently volunteering to participate in Aim 2 of the study to test an opioid overdose harm reduction intervention that was adapted by the investigators and a group of up to 8 individuals in Aim 1. Harm reduction is an approach that provides resources to reduce the potential harms and health consequences of drug use. Ultimately, our goal is to develop ways to improve access, motivation, and confidence using Narcan for opioid overdose reversal and using fentanyl test strips (FTS) to check drug supplies for the presence of fentanyl before using. This page gives you key information to help you decide whether to participate. We have included detailed information about the study after this page. Please feel free to ask the research team any questions. If you have questions later, the contact information for the research investigators in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?
By participating in this study, we will learn more about the unique barriers, challenges, and strengths regarding utilization of harm reduction resources in Black communities. In Aim 2 of this study, we will test the initial effectiveness and feasibility of an opioid overdose harm reduction intervention that was developed in Aim 1 of this study. We are asking you to participate in a one session group intervention with a survey before and after, followed by a one-time qualitative focus group in Aim 2.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?
By volunteering to participate in this study, you may help to reduce the negative impacts of the opioid epidemic for Black American individuals, families and communities in Kentucky and Ohio. You may feel empowered by your involvement in research that could improve treatment and access to culturally relevant resources and have a positive impact on community policy and practice. The THRIVE study will generate important information that can serve as the foundation to culturally-tailor treatment approaches and improve treatment outcomes among Black Americans. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?
To the best of our knowledge, answering questions and participating in the intervention and qualitative focus group in Aim 2 have no more risk of harm than you would experience in everyday life. However, if answering questions in the qualitative focus group or on the survey cause you to feel emotional distress, you may choose not to answer questions, or you may choose to stop participating. You can also choose not to participate in survey questions. If you do not want to be in the study, there are no other choices except to not take part in the study. For a complete description of risks, refer to the Detailed Consent. Further, if you do not want to be audio-recorded, you may choose to not participate in the study. If you are not willing to be audio-recorded, there is no alternative option, thus, you will be asked to withdraw from the study.

DO YOU HAVE TO TAKE PART IN THE STUDY?
If you decide to take part in the study, it should be because you want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?
The people in charge of the study are Brittany Miller-Roenigk, PhD and Danelle Stevens-Watkins, PhD, of the University of Kentucky's Department Educational, Counseling and School Psychology, and Paris Wheeler, PhD, of the University of Cincinnati's Department of Psychology. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, you can contact the study directors at: brittany.miller-roenigk@uky.edu or paris.wheeler@uc.edu, or call (513) 556-1518.

University of Cincinnati Primary Investigator is Paris Wheeler, PhD, 24-hour emergency contact: (513) 556-1518.

Research will take place at the University of Cincinnati in Clifton Court Hall or in a private room at the Urban Minority Alcoholism and Drug Abuse Outreach Program (UMADAOP).

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) during business hours (8am-5pm EST), Monday-Friday at (859) 257-9428 or toll free at 1-866-400-9428. Alternatively, contact staff at the University of Cincinnati Human Research Protection Program at 513-558-5259 during business hours (8am-5pm EST).
Or, please call the University of Cincinnati Institutional Review Board at 513-558-5259 (Monday-Friday 8am to 5pm) if you:

- Think the research has hurt you.
- Have general questions about giving consent or your rights as a research participant in this research study.
- Have questions, concerns, suggestions and/or complaints about the research.
- Cannot reach the research team or you want to talk to someone else.

To report complaints or concerns to an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?
You would be excluded from voluntarily participating in this study in Aim 2 of this study if you do not self-identify as Black or African American, are not willing to be audio-recorded during the qualitative focus group, you do not speak English, you are not at least 18 years of age, you are older than 65 years of age, or if you have not used an opioid and/or a stimulant drug not prescribed to you or in a way that was not prescribed (e.g., more than prescribed) in the past six months. Further, you will not be eligible to participate in Aim 2, if you completed Aim 1 of the study.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?
For Aim 2 of the study, focus groups will be conducted at one of two possible locations depending on your city of residence: a private room at the LCCC in Louisville, KY, a private room in Clifton Court Hall at the University of Cincinnati in Cincinnati, OH, or a private room at UMADAOP in Cincinnati, OH. You will need to come once for Aim 2, and this study visit will take about 90 to 120 minutes. The total amount of time you will be asked to volunteer for this study is about 90 to 120 minutes.

WHAT WILL YOU BE ASKED TO DO?
Aim 2 Intervention, Survey, and Focus Group: You will meet in person with a group of approximately 8-10 individuals, though potentially less, plus up to four study team members for about 90 to 120 minutes. You will complete a brief survey prior to participating in a harm reduction intervention as a group. You will then complete another brief survey after the intervention to assess your perceptions about harm reduction. After the post-intervention survey, the group will participate in a qualitative focus group to be asked for feedback on the quality and overall impressions of the intervention; feasibility of the intervention; the extent to which you believe the intervention will be helpful in improving harm reduction practices among Black individuals; additional changes you recommend; perceived knowledge and motivations related to topics of the intervention; and any additional barriers you expect with implementation of the adapted intervention. These responses will be audio-recorded with HIPAA-compliant Zoom software with your permission. Audio-files will be transcribed by Rev, a professional and confidential transcription service. Audio-files will be stored on a password protected, encrypted, HIPAA compliant University OneDrive and will be kept for 90-days. Audio-files will be transcribed within 90 days of the focus group and audio files will be destroyed or erased using a data overwriting software per University policy. Transcriptions will be de-identified and will not have your name or identifying information.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?
Some of the questions that you will be asked are sensitive and personal, including drug use, which may be uncomfortable. You may also feel uncomfortable in a group setting. We stress the importance of keeping the identities and discussions talked about in these sessions confidential and to not share outside of the research context. You do not have to answer any questions that you do not want to answer. You can stop answering

questions or quit participating at any time, and this will not affect your participation in services in any way. 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?
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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.

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There are no costs to you for participating in the THRIVE study. However, if you choose to text or use a cell phone to contact our study staff you may incur fees from your cell phone carrier. Further, if you use public transportation or ride share to get to our study site, you may incur the expense of those services. Please email us at thrivestudy@uky.edu if you would like to discuss potential assistance with transportation costs.

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When we write about or share the results from this study, we will write about the combined information. 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. All materials will be used for research purposes only and will remain strictly confidential. Individual survey data, transcripts, will only be identified by a participant's unique ID number. The master list of names and study ID numbers will be stored in a separate location from the research forms. Notably, audio-recordings will be sent to professional and confidential transcription service (Rev) for transcribing. While they have confidentiality policies to prevent unauthorized use, we are unable to guarantee confidentiality and privacy through use of third-party applications. As a safeguard, if you do not want your name on the recording, do not state your name during the focus group session. After transcription, transcripts will be de-identified for storage and use to the research team. Given the focus group nature of the study, we are unable to guarantee confidentiality of information shared in the focus group. However, it is important to not share information learned from others in the focus group with anyone outside of the research context. If you do not feel comfortable participating in a focus group, you may withdraw from the study. The participant database will be password protected and stored on a computer/server that is also password protected within a locked office. All data will be kept in locked file cabinets at the LCCC or in a private office at the University of Cincinnati. Only this study's research staff will have access to this confidential information. Agents of the University of Cincinnati will be granted access to the research records and will use every effort to protect the confidentiality to the extent permitted by law. Identifying research data will **not** be shared with any other individual or community-based organization. All study records will be maintained for six years after completion of study. Thereafter, records that contain your identifying information will be destroyed or erased using data overwriting software per University policy and sponsor directives. Information that could identify you will be removed from the study data. After removal, the study data could be used for future research studies. The study data could also be given to another researcher for future research studies. This may be done without getting additional permission from you.

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- 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

- About you if it involves a reportable disease.

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Aim 2 is a phase 1 clinical trial, where investigators are pilot testing the feasibility of an adapted harm reduction intervention. Thus, aggregate demographic information will be reported in ClinicalTrials.gov. No identifiable information or individual research data will be shared. A Phase I study is the first step in testing an investigational intervention in humans. An investigational intervention, in this phase, has not been shown to be effective in treating a condition or changing behavior and has not been approved by any federal entity. The purpose of a Phase I study is to find the best way to give an intervention and how feasible it is to implement.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave Aim 2 of this 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,
- 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 Aim 2 of this study if you are currently involved in another research study, unless you participated in Aim 1 of the study. It is important to let the investigator/your doctor know if you are in another research study. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this 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 participating in this study, you should call Paris Wheeler, PhD at (513) 556-1518 or Brittany Miller-Roenigk at brittany.miller-roenigk@uky.edu immediately.

It is important for you to understand that neither the University of Kentucky nor the University of Cincinnati 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 and the University of Cincinnati 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 a $50 gift card upon completion of your study visit in Aim 2. You will also receive Narcan and Fentanyl Test Strips (FTS) at the study visit.

WHAT IF NEW 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 Aim 2 of 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?
If requested, at the completion of the study, we will provide you with individual research results of the completed pre-and post-intervention surveys. This information will include any changes you report from before the intervention in Aim 2 to afterwards. If you want this information, please request it from request Paris Wheeler, PhD, paris.wheeler@uc.edu (513) 556-1518 or Brittany Miller-Roenigk, PhD brittany.miller-roenigk@uky.edu and we will verbally give you this data.

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). For example, do you give permission for us to share with you unexpected or expected findings related to overdose risk or harm reduction? Communications will be made by contacting the participant's contact number.

☐ 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 Paris Wheeler, PhD, paris.wheeler@uc.edu (513) 556-1518 or Brittany Miller-Roenigk, PhD brittany.miller-roenigk@uky.edu.

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 additional studies. If so, it will be limited to two times per year.

Do you give your permission to be contacted in the future by Paris Wheeler, PhD or Brittany Miller-Roenigk, PhD or their staff 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 Aim 2 of this study, you will be one of about 48-60 people to do so across all focus groups. Prior to Aim 2, up to 8 additional individuals participated in the focus groups for Aim 1 of the study to adapt a harm reduction intervention. The National Institutes of Health, the University of Kentucky CCTS, and the University of Cincinnati CCTST are providing financial support for this study.

WILL YOUR INFORMATION (OR SPECIMEN SAMPLES) BE USED FOR FUTURE RESEARCH?
All identifiable information (e.g., your name) will be removed from the information collected in this study. This means that your identity will not be kept. After identifiers have been removed, the information may be used for future research or shared with other researchers without your additional informed consent. Once you give your permission to have your de-identified information or samples stored, they will be available indefinitely.

WHAT IF YOU CHANGE YOUR MIND AND WANT TO WITHDRAW YOUR INFORMATION?
You may withdraw your permission to allow your information to be used for future research. To do so, you must send a written withdraw request to either Brittany Miller-Roenigk, PhD, 251C Scott St., Lexington, KY 40506; or Paris Wheeler, PhD, Department of Psychology, 2800 Clifton Ave Room 3230, Cincinnati, OH 45221.

Data collected from your participation in the study will remain in the study database and may not be removed, however, we will indicate that your information is not to be used for future research. We will be unable to withdraw the information that have already been used.

WILL YOU RECEIVE ANY COMMERCIAL PROFIT FROM FUTURE RESEARCH DISCOVERIES?
The information that you provide in this study 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

This consent includes the following:

- Key Information Page
- Detailed Consent

You will receive a copy of this consent form after it has been signed.

Signature of research subject	**Date**
Printed name of research subject	
Printed name of person obtaining informed consent	Date