

This document includes the following consents that were used in the *Leveraging Implementation Science to Increase Access to Trauma Treatment for Incarcerated Drug Users* study (IRB# 229172).

They are:

- Version#: 3 Date: 3/7/2019 (1 page)
- Version#: 3 Date: 3/7/2019 (2 pages)
- Version#: 3 Date: 5/6/2021 (4 pages)
- Version#: 8 Date: 2/13/2022 (8 pages)

STUDY TITLE: Leveraging Implementation Science to Increase Access to Trauma Treatment for Incarcerated Drug Users

PRINCIPAL INVESTIGATOR

Melissa J. Zielinski, Ph.D., Department of Psychiatry, University of Arkansas for Medical Sciences

STUDY SPONSORS: National Institute on Drug Abuse & University of Arkansas for Medical Sciences

PURPOSE: You are being asked to join a research study. The purpose of the study is to learn more about how to implement therapy groups for incarcerated trauma survivors who have a history of problematic drug or alcohol use. “Trauma” means life events that involve directly experiencing, seeing, or learning of actual or threatened death, serious injury, or sexual violence. We are particularly interested in your perspective on our plan to implement *Cognitive Processing Therapy (CPT)*, a gold-standard trauma therapy. We will interview 26 people, including 10 incarcerated persons and 16 prison stakeholders (e.g., Warden, counselors, and staff). We are interested in interviewing you as a part of the prison stakeholder group.

WHAT WILL HAPPEN IN THE STUDY?

If you decide to be part of the study, I will do an interview with you that will last up to 90 minutes. I will record the interview so that the interview can be transcribed and referred back to later. I will first ask you questions about yourself, such as your name, your job title, what you do in your role, how long you have been in that role, and how long you have been working for your organization. I will then ask questions about how you think that various factors will affect implementation of CPT in the prison setting, with persons who have a history of problematic drug use. Finally, you will complete up to 30 minutes of questionnaires on paper. These questions will ask you how trauma-informed you believe the prison you work with is currently. You can skip any questions you don't want to answer.

DO I HAVE TO PARTICIPATE?

No, you do not have to be part of the study. You get to choose whether you want to participate or not. Nothing about your employment status will change as a result of your decision or as a result of any answers you provide to my questions. You can stop being in the study at any time during our meeting today. Just let the interviewer know if you change your mind about participating and we will end the meeting and not use any information you might have already given us.

WILL I BE PAID FOR BEING IN THE STUDY?

Yes. We will give you \$30 cash to compensate you for your time spent participating in the study.

WHO CAN SEE THE INFORMATION I GIVE DURING THE STUDY?

The answers that you give in the study are confidential. Only the study team and people who are in charge of making sure that studies at UAMS are run the right way will have access to your information. They will keep your information in a locked file and/or password-protected computer file. Any results shared with others will be based on the answers of everyone who participated, not a particular person. This means that no individual information will be shared with your supervisors either.

CONTACT: This study is being done by Dr. Melissa Zielinski at the University of Arkansas for Medical Sciences. If you have any questions, concerns or complains about the research or to report a research-related injury, you can call Dr. Zielinski at 501-526-8229. You can also call the office that supervises research (the Institutional Review Board) at 501-686-5667 for questions about research subject's rights or to speak with someone independent of the research team.

STATEMENT OF THE SUBJECT

The purpose and voluntary nature of this study, as well as the potential benefits and risks that are involved have been explained to me. I have been able to ask questions and express concerns, which have been satisfactorily responded to by the study team. I have also been given a copy of this consent form.

STUDY TITLE: Leveraging Implementation Science to Increase Access to Trauma Treatment for Incarcerated Drug Users

PRINCIPAL INVESTIGATOR

Melissa J. Zielinski, Ph.D., Department of Psychiatry, University of Arkansas for Medical Sciences

STUDY SPONSORS: National Institute on Drug Abuse & University of Arkansas for Medical Sciences

PURPOSE: You are being asked to join a research study. We want to learn more about therapy groups for people in prison who have had traumatic experiences and had problems with drugs or alcohol. We especially want to understand what you think about *Cognitive Processing Therapy (CPT)*, a gold-standard trauma therapy we will tell you about. We are planning to interview 26 people, including 10 incarcerated persons and 16 prison stakeholders (e.g., facility Warden, counselors, and staff).

WHAT WILL HAPPEN IN THE STUDY?

If you would like to be part of the study, I will first need to see if you qualify. I will ask you about 1) traumatic experiences you may have had and possible effects of those events and 2) your drug/alcohol use. "Trauma" means life events in which you directly experienced, saw, or learned of actual or threatened death, serious, injury, or sexual violence. I will also ask a few questions about your parole plans. If you qualify and still want to participate, I will do an interview with you that will last about 1 hour. I will record the interview so that the interview can be transcribed. I will first ask you questions about yourself, like how long you have been incarcerated in this facility. I will then ask questions about what you think of the trauma therapy I mentioned. Finally, you will answer up to 30 minutes of questions on paper. Examples of some of the most sensitive questions you will be asked to answer are: "Have you ever experienced a sexual assault by a family member or someone you know?" and "In the last week, have you had thoughts that you would be better off dead or of hurting yourself in some way?". You can skip any questions you don't want to answer.

DO I HAVE TO PARTICIPATE?

No, you do not have to join the study. You can choose whether to join or not. Nothing about your incarceration, legal status, medical care, or treatment in the community corrections center will change no matter what you decide. You can stop being in the study at any time during our meeting today. Just let me know if you want to stop and we will end the meeting and not use any information you might have already given us.

WILL I BE PAID FOR BEING IN THE STUDY?

Yes. If you qualify for the study and complete an interview, we will deposit \$30 in your inmate account. This is to thank you for your time. We are not able to provide compensation for completing screening only.

WHO CAN SEE THE INFORMATION I GIVE DURING THE STUDY?

The answers that you give in the study are confidential. Only the study team and people who help make sure studies at UAMS are run the right way will have access to your information. We will keep your information in a locked file and/or password-protected computer file. The recordings may include your name, but your name will not be included in transcriptions of the interview. Any results shared with others will be based on the answers of everyone who participated, not a particular person. No one in the community corrections center will have access to your individual information. Because this study is federally funded, your participation in the research is covered by a Certificate of Confidentiality and protected from forced or compelled disclosure.

HIPAA RESEARCH AUTHORIZATION INFORMATION: We are asking you to take part in the research described in the consent form. To do this research, we need to collect health information that identifies you. We will only collect information from you that is needed for the research including: your name and prisoner ID and assessment of psychological well-being and substance use. Participating in this research study will create the following new health information: mental health assessments (including whether or not you meet criteria for certain diagnoses), record of your trauma history, record of your drug and alcohol history. For you to be included in this research, we need your permission to create and collect this information.

We will, or may, share your health information with people at the University of Arkansas for Medical Sciences (UAMS) who help with the research or things related to the research process, such as the study staff, the UAMS Institutional Review Board and the research compliance office at the University of Arkansas for Medical Sciences. *We currently do not plan to share your information with researchers outside of the University of Arkansas for Medical Sciences, although we may choose to do so in the future with approval from the IRB.* Additionally, we may need to share your health information with people outside of UAMS who make sure we do the research properly, such as the Office for Human Research Protections.

This authorization to collect and use your health information does not expire, as we may wish to continue using information we obtain after the end of this study. If you choose to be part of the study, you are giving us permission to create and collect your health information as described in this form. If you choose to be part of the study but decide later that you no longer want us to collect your health information, you must send a letter to Dr. Zielinski (see contact section below for instructions). The letter needs to be signed by you, should list the "Study Title" listed on this form, and should state that you have changed your mind and that you are revoking your "HIPAA Research Authorization". In order to maintain the reliability of the research, we may still use your information that was collected before the date the Principal Investigator received your letter withdrawing the permissions granted under this authorization.

CONTACT: Dr. Melissa Zielinski at the University of Arkansas for Medical Sciences is leading this study. If you have any questions, concerns or complaints about the research, you can call Dr. Zielinski at 501-526-8229. If you want to revoke your HIPAA authorization, you can mail your letter to her to this address:

Dr. Melissa Zielinski
University of Arkansas for Medical Sciences
Psychiatric Research Institute
4301 W. Markham Street
Little Rock, AR 72205

You can also call the office that supervises research (the Institutional Review Board) at 501-686-5667 for questions about your rights as a research subject or to speak with someone not on the research team.

STATEMENT OF THE SUBJECT

The purpose and voluntary nature of this study, as well as the potential benefits and risks that are involved have been explained to me. I have been able to ask questions and express concerns, which have been satisfactorily responded to by the study team. I have also been given a copy of this consent form.

Study Title: Leveraging Implementation Science to Increase Access to Trauma Treatment for Incarcerated Drug Users

PI: Melissa J. Zielinski, Ph.D.

Sponsor: National Institute on Drug Abuse

Institution: University of Arkansas for Medical Sciences

KEY INFORMATION FOR THE STUDY TITLED “LEVERAGING IMPLEMENTATION SCIENCE TO INCREASE ACCESS TO TRAUMA TREATMENT FOR INCARCERATED DRUG USERS”

We are asking you to choose whether or not to volunteer for a research study about how to implement therapies for incarcerated trauma survivors who have a history of problematic drug or alcohol use. We will study the effectiveness of two therapies compared to one another. We will also study how well the strategies that are used to implement the therapy group work in correctional settings.

This page gives you key information to help you decide whether to participate. We have included more detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

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

By doing this study, we hope to learn how well certain types of therapy for trauma survivors work for people who are incarcerated. We also hope to learn more about how to implement the therapies in a way that works well in correctional settings and is sustainable for correctional staff. Your participation will last for the period leading up to and following enrollment of prisoners in the therapy groups, or about 2.5 years. You will be asked to answer brief self-report measures twice. The measures will ask for your feedback on the therapy groups being studied. You will also be asked to do an interview about the treatments offered twice (once directly after enrollment ends and then 12 months later). You will also have ongoing contact with the research team to implement and track engagement in the therapies.

WHY MIGHT I CHOOSE TO VOLUNTEER FOR THIS STUDY?

Understanding *how* to effectively implement group therapy for trauma in prisons is needed. We know from past research that trauma, mental health, and drug use are all linked to incarceration from past research. Your participation in this study will help the research team know more about how to help prisons effectively treat negative trauma-related outcomes.

WHY MIGHT I CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Participating in the study will require you to commit some time to filling out questionnaires and doing interviews. You may already feel you are too busy to participate or may not want to share your opinions.

DO I HAVE TO PARTICIPATE?

No. It is okay to say no. 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.

WHAT IF I HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?

You can contact the person in charge of the study, Dr. Melissa Zielinski at UAMS' Psychiatric Research Institute, with any questions, suggestions or concerns. You can reach her by phone at 501-526-8229 or by email at MJZielinski@uams.edu.

If you have any questions, suggestions, or concerns about your rights as a volunteer in this study or wish to talk to someone not directly involved in the research, you can call the UAMS Institutional Review Board at 501-686-5667 during business hours.

If you want to know more about the research, let the study team know so they can give you more information.

Also tell the study team if you have decided you don't want to be in the study. It is perfectly okay to say no.

Study Title: Leveraging Implementation Science to Increase Access to Trauma Treatment for Incarcerated Drug Users

PI: Melissa J. Zielinski, Ph.D.

Sponsor: National Institute on Drug Abuse

Institution: University of Arkansas for Medical Sciences

University of Arkansas for Medical Sciences Consent Form

Principal Investigator

Melissa J. Zielinski, Ph.D., Department of Psychiatry
University of Arkansas for Medical Sciences
4301 West Markham St Little Rock, AR 72205
Phone Number: 501-500-4830

Researcher's Statement

We are asking you to be in a research study. Participation is voluntary and confidential. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be in the study. We will review the form carefully together. If any of this information is unclear to you, please let us know so that we may clarify. When we have answered all your questions, you will have the opportunity to decide whether you consent or decline to be a participant in this research study. This process is called "informed consent." We will give you a copy of this form for your records.

- **We are asking you to be in a research study. You do not have to join the study.**
- **You can still get your medical care from UAMS even if you are not in the study.**
- **Please take as much time as you need to read this form and decide what is right for you.**

Why am I being asked to be in this research study?

There are two main goals of this research study. The first goal is to test two different therapies for incarcerated trauma survivors who have a history of problematic drug or alcohol use. The second goal is to study methods for how to implement therapies in a way that works well in the correctional setting and is sustainable for correctional staff.

We are asking people like you, who are involved in delivering or supervising group programs in prisons to help us. We expect that about 10 providers/supervisors and 210 prisoners will be a part of the study.

What if I don't understand something?

This form may have words you don't understand. If you'd like, research staff will read it with you. You can ask questions at any time – before, during, and after you are in the study. Please ask as many questions as you like before you decide whether you want to be in the study.

What will happen if I say that I do want to be in this study?

Participation is voluntary. If you choose to participate in the study, you will:

- Take some surveys and complete an interview about how you feel about the study therapies and the methods used to implement these therapies. The surveys and interview will be done twice during the 2.5 year period, and will take about 30 minutes each time. Interviews will be audio-recorded so that they can be transcribed and analyzed later.
- If you are providing the study therapy or helping with implementation, you will also work with the research team on an ongoing basis to implement and track implementation of the therapy. This will include things like working together to: establish a schedule, monitor therapy attendance, monitor if the therapies are being implemented as intended, and arrange meetings with therapy participants.

Study Title: Leveraging Implementation Science to Increase Access to Trauma Treatment for Incarcerated Drug Users

PI: Melissa J. Zielinski, Ph.D.

Sponsor: National Institute on Drug Abuse

Institution: University of Arkansas for Medical Sciences

What will happen if I say that I do not want to be in this study?

Participation in the interviews and surveys is voluntary. If you do not want to complete them nothing bad will happen. You can still get medical care at UAMS. If you have been selected by your organization to be a study therapist or help with implementation, you would still continue serving in those roles.

What happens if I say yes, but change my mind later?

Please call the person in charge of the study, Dr. Melissa Zielinski at UAMS' Psychiatric Research Institute, at 501-526-8229 if you no longer want to participate in surveys and interviews. She will remove you from the list for future contacts. Nothing bad will happen as a result and you can still get medical care at UAMS.

Will being in this study help me in any way?

Being in this study may or may not help you, but may help people who have symptoms of PTSD and addiction who become incarcerated. What we learn may also help people like you who work in prison systems and want to implement evidence-based therapies in the future because we are also studying the process by which the study therapies are implemented.

What are the risks of being in this study?

The risks for this study are no more than what happens in everyday life. It is possible that someone could find out that you were in the study and learn something about you that you did not want others to know. We will do our best to protect your privacy.

Can I be taken out of the study even if I want to continue?

Yes, the head researcher can take you out of the study. If you leave your current position, you may be withdrawn depending upon how the timing of your departure overlaps with other study activities.

What information will be collected about me in the study?

During the study, we will need ask private things about you including:

- General contact and background information about you, like your name, telephone number, and other demographic information.
- Your opinions about the population you work with.
- Your opinions about the study therapies and strategy for implementing these therapies, including how well they do or do not work within your organizational context.

Who will see this information? How will you keep it private?

The local study team will know your name and have access to your information. Because of the close nature of correctional centers, it is possible that others will know that you are participating in the study; however, the research team will not share this information or any information that you provide us with directly. When we share the results of the study (for example, in presentations to your organization or in academic presentations/publications), we will not include your name or anything else that identifies you. We will not take your name off of information we collect directly from you during the study. It will be kept in locked and/or password protected storage accessible to only the local study team, however.

There are people who make sure that the study is run the right way. These people may see information from the study about you. They are:

- The National Institute on Drug Abuse (study sponsor)
- OHRP (Office for Human Research Protections), a federal agency
- UAMS Institutional Review Board
- Other institutional oversight offices

State law requires that we tell the authorities if we learn about possible child or adult abuse or if we learn that you might hurt yourself or someone else.

Study Title: Leveraging Implementation Science to Increase Access to Trauma Treatment for Incarcerated Drug Users

PI: Melissa J. Zielinski, Ph.D.

Sponsor: National Institute on Drug Abuse

Institution: University of Arkansas for Medical Sciences

Where and how long will my information be kept?

Sometimes researchers destroy participants' information after a certain period of time has passed. We have no plans to destroy information obtained during this study at this time and plan to store all of your records indefinitely. However, we plan to digitally scan and will subsequently destroy paper copies of your records after the study has closed. This will allow us to keep copies of your records if they are needed to check for accuracy in the future, while limiting long-term storage of your responses to computerized versions only.

If I stop being in the study, what will happen to any information collected from me in the study?

We will not be able to take your information out of the study after it has started.

Will my information from the study be used for anything else, including for future research?

No. Your information will only be used for the purposes of this study. It will not be used for future research or anything else unrelated to this study.

Will you tell me the results of the study?

Yes. We will tell you about anything important that we discover from the study if you are still employed in a participating organization by the time that the research has been completed. If you are no longer employed there and would like to receive a copy of the results at a later time, please email the person in charge of the study, Dr. Melissa Zielinski, at MJZielinski@uams.edu to let her know you would like study results.

Where can I find more information about this clinical trial?

A description of this clinical trial will be available on <http://www.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 any time.

By moving forward with this study, I am saying:

- ✓ I understand that joining this study is voluntary.
- ✓ I agree to be in the study.
- ✓ Someone talked with me about the information in this document and answered all of my questions.

I know that:

- ✓ I can stop any and all parts of the study at any time and nothing bad will happen to me.
- ✓ I can call the office that supervises research (UAMS Institutional Review Board) at 501-686-5667 if I have any questions about the study or about my rights.
- ✓ I do not give up any of my rights by signing this form.
- ✓ My decision will not change my medical care at UAMS.

Study Title: Leveraging Implementation Science to Increase Access to Trauma Treatment for Incarcerated Drug Users

PI: Melissa J. Zielinski, Ph.D.

Sponsor: National Institute on Drug Abuse

Institution: University of Arkansas for Medical Sciences

KEY INFORMATION FOR THE STUDY TITLED “LEVERAGING IMPLEMENTATION SCIENCE TO INCREASE ACCESS TO TRAUMA TREATMENT FOR INCARCERATED DRUG USERS”

We are asking you to choose whether or not to volunteer for a research study about how to make trauma therapies available for incarcerated trauma survivors who have a history of problematic drug or alcohol use. We will study the effectiveness of two therapies compared to one another. We will also study how the well the strategies used to support the therapies work in the prison setting.

This page gives you key information to help you decide whether to participate. We have included more detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

Participation in this study will not change anything about your incarceration or eligibility for parole.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST? We hope to learn how well certain types of therapy for trauma survivors work for people who are in prison and who have had problems with drug or alcohol use. You should understand that although these therapies address some topics related to drug and alcohol use, the main focus of these therapies is on trauma recovery. We also hope to learn about how to support the therapies in a way that works well in prison and is sustainable for staff. These therapies are experimental. If you qualify, you will be randomly assigned (like flipping a coin) to one of the two study therapies. You will complete this study therapy before getting out of prison. You will also answer surveys and interviews three times (twice while you are in prison and once about 3 months after you leave prison). This means that your participation could last as short as about 6 months and as long as about 15 months.

WHY MIGHT I CHOOSE TO VOLUNTEER FOR THIS STUDY? We know from past research that trauma, mental health, and drug use are all linked to incarceration. Your participation in this study will help the research team know more about how to help prisons treat mental health problems related to trauma.

WHY MIGHT I CHOOSE NOT TO VOLUNTEER FOR THIS STUDY? Participating in the study will require you to commit your time to the treatment and research activities. You may already feel you are too busy to participate. You may also find talking about past trauma distressing or not be ready for a therapy that focuses on traumatic experiences and drug and alcohol use at this time.

DO I HAVE TO PARTICIPATE? No. It is okay to say no. 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. Nothing about your incarceration, legal status, medical care, or treatment in the community corrections center will change no matter what you decide.

WHAT IF I HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS? You can contact the person in charge of the study, Dr. Melissa Zielinski at UAMS’ Psychiatric Research Institute. You can reach her by phone at 501-526-8229 or by email at MJZielinski@uams.edu. If you have any questions, suggestions, or concerns about your rights as a volunteer in this study or wish to talk to someone not directly involved in the research, you can call the UAMS Institutional Review Board at 501-686-5667 during business hours.

If you want to know more about the research, let the study team know so they can give you more information.

Also tell the study team if you have decided you don’t want to be in the study. It is perfectly okay to say no.

Study Title: Leveraging Implementation Science to Increase Access to Trauma Treatment for Incarcerated Drug Users

PI: Melissa J. Zielinski, Ph.D.

Sponsor: National Institute on Drug Abuse

Institution: University of Arkansas for Medical Sciences

University of Arkansas for Medical Sciences Consent Form

Principal Investigator

Melissa J. Zielinski, Ph.D., Department of Psychiatry
University of Arkansas for Medical Sciences
4301 West Markham St Little Rock, AR 72205
Phone Number: 501-526-8229

Researcher's Statement

We are asking you to be in a research study. Participation is voluntary and confidential. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be in the study. We will review the form carefully together. If any of this information is unclear to you, please let us know so that we may clarify. When we have answered all your questions, you will have the opportunity to decide whether you consent or decline to be a participant in this research study. This process is called "informed consent." We will give you a copy of this form for your records.

- **We are asking you to be in a research study. You do not have to join the study.**
- **You can still get your medical care from UAMS even if you are not in the study.**
- **Please take as much time as you need to read this form and decide what is right for you.**

Why am I being asked to be in this research study?

There are two main goals of this research study. The first goal is to test two different therapies for incarcerated trauma survivors who have a history of problematic drug or alcohol use and compare them to one another. The second goal is to study methods for how to support therapies in a way that works well in the prison setting and is sustainable for prison staff.

We are asking people like you, who are incarcerated and who have experienced trauma and used drugs/alcohol, to help us. "Trauma" means life events in which you directly experienced, saw, or learned of actual or threatened death, serious injury, or sexual violence. We expect that about 210 people who are incarcerated will be a part of the study.

What if I don't understand something?

This form may have words you don't understand. If you'd like, research staff will read it with you. You can ask questions at any time – before, during, and after you are in the study. Please ask as many questions as you like before you decide whether you want to be in the study.

What are the types of therapy being offered in the study?

There are two types of therapy that you can be assigned to if you choose to participate in the study. Each person will be randomly assigned (like flipping a coin) to one or the other. You cannot choose which study treatment you receive. One therapy is called CPT-CJ, which stands for Cognitive Processing Therapy-Criminal Justice Version. CPT-CJ sessions combine education about trauma with teaching people how to evaluate and change upsetting thoughts that they have had since their trauma. This study therapy was modified from its original form to fit correctional centers. The other study therapy, called PTSD Coping Skills

Study Title: Leveraging Implementation Science to Increase Access to Trauma Treatment for Incarcerated Drug Users

PI: Melissa J. Zielinski, Ph.D.

Sponsor: National Institute on Drug Abuse

Institution: University of Arkansas for Medical Sciences

Group (PCS), is a coping-focused skills intervention based out of a self-help workbook called "The Cognitive Behavioral Coping Skills Workbook for PTSD" and has not been modified from its original form. In PCS, participants will receive education about trauma and PTSD and learn skills for how to cope with and manage PTSD symptoms. The materials will be compiled by a clinical psychologist who is an expert in trauma therapy. Both treatments will involve work individually and in group. Similar kinds of treatments have been found to be helpful; but, these two treatment approaches are experimental and have not been compared when delivered in prison before.

What will happen if I say that I do want to be in this study?

Participation is voluntary. If you choose to participate in the study, you will complete the following:

- Take some surveys and complete an interview three time points. Two times will be while you are in prison. One time will be after you leave prison. Each assessment will take about 3 hours. Assessments may be split into multiple parts to make it less tiring for you. You will be paid \$30 for your time for two of the assessments and \$50 for one of the assessments. If you decide to stop during an assessment, you will be paid \$5 for each 30 minutes that you spent participating, up to the maximum amount for that time point.
- Complete one of the study therapies while you are still in prison.
- Stay in contact with the research team to update contact information for about 3 months after you leave prison, and provide many ways we can potentially get in touch with you.
- If you receive more than \$600 in one year (January-December) from UAMS, we may send you a tax form if required by law.

More detail on each of the bullet points above is given here:

Baseline Visit. This first appointment will take about 3 hours and will include questions about your psychological history (for example, problems with PTSD symptoms and depression), previous trauma exposure, and substance use (drugs and alcohol). . The interview portion of the assessment will be digitally recorded to ensure that it is delivered as intended. Examples of some of the most sensitive questions you will be asked to answer during the screening and baseline visit are: "Have you ever experienced a sexual assault by a family member or someone you know?" and "In the last week, have you had thoughts that you would be better off dead or of hurting yourself in some way?" You are free not to answer any questions that you do not want to answer, though if you choose not to answer an item that is needed to tell your fit with the study you will not be able to participate.

It is possible that doing this assessment will reveal that the study is not a good match for you. If this is the case, we will pay you for participating in this visit but will not schedule you for any other study procedures.

Random Assignment to Study Condition. If you qualify for the study, we will randomly assign you to one of the two study therapies. Random assignment is like flipping a coin or pulling a name out of a hat. You will find out which study therapy you have been assigned to from the facility treatment coordinator before group starts.

Treatment. All treatment will be completed while you are still in prison. In both therapies, our goal is that you will start your assigned study therapy within about 4 weeks of the completion of your pre-treatment assessment. You will then go to sessions according to the schedule set by the facility treatment coordinator and study team. You will receive a copy of this schedule once you are randomly assigned to a treatment. Both treatments involve group and individual meetings over about 8-12 weeks. Regular attendance is important, as there will not typically be make up sessions available if you miss an appointment. Because of the COVID-19 pandemic, it is possible that there will be interruptions to your treatment; for example, if the prison restricts movement in the facility, your treatment group may not be able to meet until the restrictions

Study Title: Leveraging Implementation Science to Increase Access to Trauma Treatment for Incarcerated Drug Users

PI: Melissa J. Zielinski, Ph.D.

Sponsor: National Institute on Drug Abuse

Institution: University of Arkansas for Medical Sciences

are lifted. If this occurs, we will work with the facility to resume as soon as possible and will do our best to help you keep making progress on your own (e.g., by giving you instructions for how to continue working through the group material on your own).

Assignments that you complete as a part of the study will be shared with members of the research team at times. Also, some information shared during the sessions will be discussed by the therapist and research team and sessions may be observed by the PI of the study through televideo. This is necessary so that the counselors providing the study therapy can receive supervision from experts and so that we may improve the therapy materials based on your experience.

Follow-Up Assessments. Everyone will be asked to do two follow-up assessments. The first follow-up assessment will happen within about three weeks of when the study therapy group you are assigned to has ended. You will complete this assessment while you are still in prison. The second follow-up assessment will happen about 3 months after you are released from prison. The research team will work with you to find a good and private location for the assessment. Each of these assessments will ask you about your mental health, substance use, and psychological well-being, as well as your feedback on the study therapy you complete. They will also ask for psychosocial information such as your age, race, and education level, as well as social support, and life circumstances. Assessments will be digitally recorded so that the research team can review your responses later..

After Study Treatment Is Complete. At the end of treatment, you may feel that the therapy you got was enough to meet your needs or you may feel that you need more treatment. If you feel that you need more treatment, you are welcome to pursue that in prison or in the community. We will give you a list of community referrals at the end of the treatment phase of the study as well as at the very end of the study. However, the study cannot provide additional treatment beyond the one group that you are randomly assigned to.

Maintaining Contact When You Leave Prison. Because the study will take place over about 6-18 months (depending on how close you are to leaving prison when you sign up), it will be important for us to be able to keep in contact with you. During each visit we will ask you for information that will help us find you after you leave prison. We will ask for many ways to try to reach you in case your phone number is disconnected or different than you are expecting after you leave prison. If people you have given us permission to reach out to give us new information for how to reach you, we will use this to try to contact you. Also, we will ask your parole office for your updated contact information if we are not able to get in touch with you through community contacts and may use other kinds of publicly-accessible information if we are stuck. We would also appreciate if you would call the study phone number when you are back in the community to update your contact information. If you do this, we may not need to contact any other sources other than talking to you directly. We will contact you regularly after you leave prison but before you complete the third follow-up assessment to update your contact information.

What will happen if I say that I do not want to be in this study?

Participation is voluntary. If you do not want to be in the study nothing bad will happen. You can still get medical care at UAMS and receive counseling while in prison. You can also continue to receive the study therapy if you have already been randomly assigned to a study treatment, but you will no longer meet with the study team to complete assessments.

What happens if I say yes, but change my mind later?

You can stop being in the study at any time. If you no longer want to participate while you are still in prison, please tell a member of the study team when they meet with you to complete an assessment. Please call the person in charge of the study, Dr. Melissa Zielinski at UAMS' Psychiatric Research Institute, at 501-526-

Study Title: Leveraging Implementation Science to Increase Access to Trauma Treatment for Incarcerated Drug Users

PI: Melissa J. Zielinski, Ph.D.

Sponsor: National Institute on Drug Abuse

Institution: University of Arkansas for Medical Sciences

8229 if you no longer want to participate after leaving prison. Nothing bad will happen as a result and you can still get medical care at UAMS. Nothing about your incarceration will change either.

Will being in this study help me in any way?

Being in this study may or may not help you. You may benefit by learning more about yourself through study participation. You may also benefit from the therapy that is provided to eligible participants. What we learn through your participation may help people who have symptoms of PTSD and addiction who become incarcerated more broadly. What we learn may also help people who work in prison systems and want to support therapies for trauma in the future.

What are the risks of being in this study?

The risks associated with participation in this study are primarily related to the sensitivity of some of the questions and to discomfort that may arise from working on PTSD symptoms in treatment. You should understand that although these therapies address some topics related to drug and alcohol use, the main focus of these therapies is on trauma recovery. You will be asked about thoughts, feelings, and personal difficulties related to trauma that may be private and feel sensitive. You will be asked about trauma exposure, substance use, and your mental health. You will also be asked about your legal history which may be linked to your incarceration record obtained from Arkansas Community Corrections (ACC). These questions may make you feel uncomfortable, bring back stressful or upsetting memories or seem intrusive. You may also become concerned about how you are coping with stressful events you have experienced as you answer the questions. In addition, you may find that talking about your substance use problems and PTSD symptoms in treatment can be upsetting, especially if you have tried very hard to avoid thinking or talking about painful things from the past. It is normal to experience an increase in emotional distress when you are actively working on such hard issues and it will be important to let study staff know if this is happening for you so they can work with you to lessen this possibility.

There is a risk of loss of confidentiality (i.e., people not involved in the research study finding out personal information about you). Answers to the questions could pose a risk if the information were known and linked to specific individuals. We have taken several steps to protect you from these risks, and these protections are described below in this document.

The particular study treatments or procedures in this study may involve risks that are currently unforeseeable. We will contact you as soon as possible if new findings occur during this research that may pose a risk to you.

What are the alternatives to being in this study?

If you don't want to join the study, you can seek any regular treatment already available to you in the prison.

Can I be taken out of the study even if I want to continue?

Yes, the head researcher can take you out of the study if you do not follow study instructions, it is not in your best interests to continue, or if the study is stopped for any reason. If you are transferred to a different prison, you may also be withdrawn from the study depending upon whether the warden at that facility allows us to contact you for follow up. If you are transferred before your treatment is complete, the study therapy will also no longer be available to you; however, we would still contact you for follow-up.

What information will be collected about me in the study?

During the study, we will need ask private things about you including:

- General contact and background information about you, like your name, telephone number, and other demographic information.
- Information about your mental health, substance use, and legal history.

Study Title: Leveraging Implementation Science to Increase Access to Trauma Treatment for Incarcerated Drug Users

PI: Melissa J. Zielinski, Ph.D.

Sponsor: National Institute on Drug Abuse

Institution: University of Arkansas for Medical Sciences

- Your incarceration records, as obtained through Arkansas Community Corrections (ACC)
- Your opinions about the study therapies and strategy for supporting these therapies.

Who will see this information? How will you keep it private?

The local study team will know your name and have access to your information. The staff at the correction center will also know that you are a part of the study, but not be able to see the detailed information that you share with our research team during assessments. Also, information shared and discussed in each session will only be shared with prison staff who are in a treatment/counseling role as their job responsibility.

Because we will be following up with you after you leave prison, we may need to tell others that you are a research participant in order to be able to meet with you. For example, we will reach out to the community contacts you give us and/or to your parole officer to get your contact information if we are having trouble reaching you after you leave prison. Also, if you are rearrested and in a different prison or jail, we will need to tell the staff that you are part of the study to be able to meet you. However, none of these people will know your study responses either. Nothing about your legal status will change as a result of your study participation or responses.

We do not currently plan to share your information with researchers outside of UAMS. However, we may choose to do so in the future with approval from the IRB. When we share the results of the study (for example, in presentations to your organization or in academic presentations/publications), we will not include your name or anything else that identifies you. We will not take your name off of information we collect directly from you during the study. It will be kept in locked and/or password protected storage accessible to only the local study team, however.

To further help us protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services. The investigators can use this Certificate to refuse to disclose information (for example if there were a court subpoena) that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for the purpose of audit or evaluation. Also, this Certificate does not prevent you or a member of your family from voluntarily releasing information about involvement in this research.

The only exception to your privacy is that state law requires that we tell the authorities if you tell us about child or adult abuse, or if we learn that you might hurt yourself or someone else. If you tell us about any information related to these things in your interview, we may have to break your privacy. Therapy leaders may also be obligated to report it if you share something during a group therapy session that makes them concerned about the safety of you or other people or about violations of facility rules. The group leaders will tell you about the types of information they may have to report during your first group therapy session if you participate.

Finally, there are people who make sure that the study is run the right way. These people may see information from the study about you. They are:

- The National Institute on Drug Abuse (study sponsor)
- OHRP (Office for Human Research Protections), a federal agency
- UAMS Institutional Review Board
- Other institutional oversight offices

Where and how long will my information be kept?

Sometimes researchers destroy participants' information after a certain period of time has passed. We have no plans to destroy information obtained during this study at this time and plan to store all of your records indefinitely. However, we plan to digitally scan and subsequently destroy paper copies of your records five

Study Title: Leveraging Implementation Science to Increase Access to Trauma Treatment for Incarcerated Drug Users

PI: Melissa J. Zielinski, Ph.D.

Sponsor: National Institute on Drug Abuse

Institution: University of Arkansas for Medical Sciences

years after the study has closed. This will allow us to keep copies of your records if they are needed to check for accuracy in the future, while limiting long-term storage of your responses to computerized versions only.

If I stop being in the study, what will happen to any information collected from me in the study?

We will not be able to take your information out of the study after it has started.

Will my information from the study be used for anything else, including for future research?

Yes, if you agree below, we may use your information for other studies. For example, we may use it to study how people who do and do not complete a group therapy for trauma while incarcerated do over a longer follow-up period. This could include looking at administrative and correctional records to determine involvement in the criminal justice system and with law enforcement from the State of Arkansas for 12 months post-release. We might also contact you again in the future to invite you to participate in an additional follow-up. Another example is that we may also look at how different assessments you complete work scientifically for people who are incarcerated (i.e., if screening measures for certain mental health problems are accurate). This will help us learn the most out of the time that you spend participating.

Will you tell me the results of the study?

No. We will not notify you directly. We will, however, publish the results of this trial in an academic journal and pursue opportunities to share the results with people who are employed by Arkansas Department of Corrections and the community more broadly. If you would like a copy of the findings once published, please email the person in charge of the study, Dr. Melissa Zielinski, at MJZielinski@uams.edu to let her know.

Where can I find more information about this clinical trial?

A description of this clinical trial will be available on <http://www.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 any time.

By signing this document, I am saying:

- I understand that joining this study is voluntary.
- I agree to be in the study.
- Someone talked with me about the information in this document and answered all of my questions.

I know that:

- I can stop any and all parts of the study at any time and nothing bad will happen to me.
- I can call the office that supervises research (UAMS Institutional Review Board) at 501-686-5667 if I have any questions about the study or about my rights.
- I do not give up any of my rights by signing this form.
- My decision will not change my medical care at UAMS.

My Name (Please Print)

My Signature

Today's Date

Printed Name of Person Obtaining Consent

Signature

Today's Date

Study Title: Leveraging Implementation Science to Increase Access to Trauma Treatment for Incarcerated Drug Users

PI: Melissa J. Zielinski, Ph.D.

Sponsor: National Institute on Drug Abuse

Institution: University of Arkansas for Medical Sciences

ADDITIONAL PERMISSIONS

Future Studies

We may want to utilize the information you share in this study in different studies in the future. Future studies may investigate things like the effects of or process used to support study treatment services in the correctional setting or changes in health status or criminal justice involvement of people who did and did not complete a trauma therapy group while incarcerated over time. They may also scientifically look at how well the measures you complete work for people in prison.

Please initial one of the below options:

Yes, I consent for my records to be used in future research studies.

No, please do not utilize my records for future studies.

We may want to contact you to invite you to participate in a different study in the future. If we do contact you, you would not be obligated to participate – you could decide if you were interested at that time.

Please initial one of the below options:

Yes, I would like to be contacted for future studies.

No, please do not contact me for future studies.