Informed Consent Form

Project Title: Reducing Stigma towards Opioid Use Disorder on Interpersonal and Intrapersonal Levels

NCT #: 20-07852

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TITLE: Reducing Stigma towards Opioid Use Disorder on Interpersonal and Intrapersonal Levels

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1. KEY INFORMATION:

You are being given the opportunity to participate in this research study. The purpose of this consent form is to help you decide if you want to be in the research study.

The purpose of this study is to evaluate a program aimed at reducing stigma (negative attitudes) towards treatment for substance use disorders in people who state they have substance use issues.

Procedures:
In this study, you will have two visits with study staff: one today and one in two weeks. Both can be completed over the phone. At each visit, we will ask you to complete some questionnaires about your attitudes towards substance use. We will also discuss some information about substance use disorder and set up a referral for treatment if you would like.

Your participation in this study will last for at most 3 weeks.

The following procedures are being performed for research purposes only:
- Discussing attitudes towards substance use,
- Making referrals for substance use treatment,
- 3 questionnaires, and
- A follow-up call in two weeks.

For a detailed explanation of the procedures, refer to the section of this consent form entitled, DETAILED PROCEDURES TO BE FOLLOWED.

Risks:
Some of the most common side effects from study participation are uncomfortable feelings during the questionnaires. There is also a small chance someone could identify you from the audio recording of our discussion, but that is very unlikely.

For a detailed list of the potential risks, refer to the section of this consent form entitled, RISKS ASSOCIATED WITH PARTICIPATION.

Benefits:
Your substance use disorder may improve while you are in this study; however, this cannot be promised.
The results of this study may help people with substance use disorder in the future by changing attitudes about treatment.

Alternatives:
You may receive treatment for substance use disorder without participating in this study.

If you decide not to enter this study, there are other choices available such as seeking treatment on your own. Ask the study investigator to discuss these alternatives with you. You do not need to be in this study to receive treatment for your condition.

If you do not participate in this study, none of the procedures described in this consent form will be performed.

Voluntary Participation:
Your participation in this research study is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

If you are a student of UTHSC, participating or not participating in this study will in no way influence your grade in any course. If you are a resident or fellow of UTHSC, participating or not participating in this study will in no way influence your academic standing. If you are an employee of UTHSC, participating or not participating in this study will not affect your employment status.

2. DETAILED PROCEDURES TO BE FOLLOWED:

A total of 90 participants will be participating in this study: 50 with substance use disorder and 40 friends or family members.

The study will take place at 66 N. Pauline St, Memphis, TN 38163.

Baseline (this will take 30 minutes today):
- 3 Questionnaires (contact info, demographics, stigma assessment)
- Stigma reduction intervention (treatment)
- Treatment referral or give materials for future treatment

Follow-Up (15 minutes two weeks from now.):
- 4 Questionnaires (contact info, demographics, stigma assessment, treatment status)

If you decide to stop being part of the study, you should tell your study investigator, and any information that you have already provided will be kept in a confidential manner.

3. RISKS ASSOCIATED WITH PARTICIPATION:

There is a risk that your private identifiable information may be seen by people not involved in the research (such as if a researcher's computer is stolen or an electronic database is hacked). However, we will use very careful security measures (such as locks on file cabinets, computer passwords, etc.) to minimize the chance that any unauthorized persons might see your confidential information.

The research may involve risks to you which are currently unforeseeable. You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

Questionnaires/Surveys:
Completion of the demographics questionnaire may make you feel uncomfortable or cause troublesome feelings or emotions. You may refuse to answer any of the questions, and you may take a break at any time during the study.

Individual counseling:
Participating in the stigma intervention may make you feel uncomfortable or cause troublesome feelings or emotions. You may take a break or end the session at any time during the study.

4. CONFIDENTIALITY:

Research records
All your electronic research records will be computer password protected and accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

Your identifiable research records will be transmitted to UTHSC using an encrypted method (not regular email), where your information is replaced with a code and password only known to the entities below).

Your private information collected as part of this research, even if identifiers are removed, will not be used or distributed for future research studies.

Medical Records
Information about your participation in this study or the results of procedures performed in this study will not be placed in your medical record.

Presentations/Publications
While individual details about your case might be provided in publications or presentations about this research, they will not be discussed in a way that would allow you to be individually identified as a participant.

Limits to Confidentiality

Information obtained during the course of the study, which in the opinion of the investigator(s) suggests that you may be at significant risk of harm to yourself or others, may be reported to a third party to protect the rights and welfare of those at potential risk.

Authorization to Use and Disclose Protected Health Information for Research Purposes
Under federal privacy regulations, you have the right to decide who can review and copy your identifiable health information (called "protected health information" or PHI). PHI collected in this study may include information such as:

- Records about your study visits
- Records about phone calls made as part of this research
- Research records

By signing this consent form, you are giving your permission for the study investigator and the study staff to potentially share your PHI with:

- The Institutional Review Board (IRB) at the University of Tennessee Health Science Center
- Department of Health and Human Services (DHHS) or other government agencies
- NIH, which sponsors and provides funds for this research

Your PHI will only be used and/or given to others:

- To do the research
- To study the results
- To see if the research was done correctly

Your PHI will be used until the study is completed.

You may withdraw or take away your permission to use and disclose your PHI at any time. You do this by sending written notice to the study investigator. If you withdraw your permission, you may not be able to stay in the study.

When you withdraw your permission, no new PHI will be gathered after that date. However, information that has already been gathered may still be used and given to others. The federal regulations allow you to review or copy your PHI that is used in this study. However, in order to complete the research, your access to this PHI may be temporarily suspended while the research is in progress. Once the study is over, your right to review and copy your PHI will be reinstated.

Certificate of Confidentiality
This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers with this Certificate may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except when: (1) there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases); (2) you have consented to the disclosure, including for your

medical treatment; or (3) the materials are used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH which is funding this project.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

5. COMPENSATION AND TREATMENT FOR INJURY:

You are not waiving any legal rights or releasing the University of Tennessee or its agents from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee does not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee does not provide for treatment or reimbursement for such injuries.

If you are injured or get sick as a result of being in this study, call the study investigator immediately. The study investigator will provide acute medical treatment and will provide you with a subsequent referral to appropriate health care facilities.

If you are injured or get sick as a result of being in this study, you and/or your insurance will be billed for the costs associated with this medical treatment.
No compensation will be available to you for any extra expenses that you may have as the result of research-related physical injuries, such as additional hospital bills, lost wages, travel expenses, etc.

No compensation will be available to you for any non-physical injuries that you may have as a result of research participation, such as legal problems, problems with your finances or job, or damage to your reputation.

6. QUESTIONS:

Contact Unjanae Johnson at 615-682-3854 if you have questions about your participation in this study, or if you have questions, concerns, or complaints about the research.

If you feel you have had a research-related injury, contact Dr. Karen Derefinko at 901-448-3099.

You may contact Cameron Barclay, MSA, UTHSC IRB Director, at 901-448-4824, or visit the IRB website at http://www.uthsc.edu/research/compliance/irb/ if you have any questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research.

7. PAYMENT FOR PARTICIPATION:

You will receive a $40 gift card to Kroger at the completion of the first study visit (today) and a $40 at the completion of your follow-up visit. If you complete all the study visits, you will receive a total of 2 gift cards worth $80.

We also have a refer-a-friend program where if someone you refer enrolls, you can receive an additional $20 gift card. You can redeem this a maximum of 2 times for a total of an additional $40.

If you complete both visits and refer two friends, you will receive a total of 4 gift cards worth $120 total.

8. COSTS OF PARTICIPATION:

There are no costs to you for participating in this study. NIH will provide the study interventions free of charge during this study.

9. FUTURE CONTACT:

If we lose contact with you during the study for any reason (your phone number changes; your physical or email address changes; you are not responding to our attempts to contact you about your continued participation; etc.), we will attempt to find you or make contact with you in the following ways:

- The phone number(s) you provided to us will be called, but if you are not the person who answers, we will not say the title of the study or the fact that you are/were participating in a study.
- A text message will be sent to the number(s) you provided asking you to call us.
- A letter will be sent to the address(es) you provided to us, but neither the return address nor any markings on the envelope will identify the title of the study or the fact that you are/were participating in a study.
- We will send you a message on Facebook if you provide us with that information.

Put your initials on one of the lines below:

_____We CAN attempt to find/contact you in the above ways.

_____We MAY NOT attempt to find/contact you in the above ways.

10. CONSENT OF SUBJECT:

You have read or have had read to you a description of the research study as outlined above. The investigator or his/her representative has explained the study to you and has answered all the questions you have at this time. You knowingly and freely choose to participate in the study. A copy of this consent form will be given to you for your records.

_____	_____	_____
Signature of Research Subject (18 years +)	**Date**	**Time**

_____

Printed Name of Adult Research Subject

_____	_____	_____
Signature of Person Obtaining Consent	**Date**	**Time**

_____

Printed Name of Person Obtaining Consent

In my judgment, the subject has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____	_____	_____
Signature of Investigator	**Date**	**Time**