UD IRB Approved: 10/25/2021
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CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of Study: UDisclose: Testing a New Disclosure Activity

Principal Investigator(s): Valerie A. Earnshaw, Ph.D.

KEY INFORMATION

Important aspects of the study you should know about first:

- **Purpose:** The purpose of the study is to test an activity we developed to help people decide whether and how they want to disclose to, or tell, others that they are in recovery from substance use disorders.
- **Procedures**: If you choose to participate, you will complete an activity focused on *either* (A) disclosure or (B) meditation with a researcher, and answer questions in a survey and out loud with a research assistant. You will be randomly assigned to the activity, like with a coin flip. After one month, we will meet with you again so that you can tell us whether and how you used what you learned. You can talk with us by phone or in person for this second visit. You do not have to disclose as part of this study. Whether or not you disclose is your choice.
- **Duration:** Your participation in this study will involve two visits, with the second visit occurring 1 month after the first visit. The first visit will last an hour or less, and the second visit will last 30 minutes or less. We will ask for your permission to send you reminders between the two visits.
- **Risks**: The main risks from this study are feeling uncomfortable and a breach in confidentiality, or someone else learning that you participated in this study. These risks are not expected to be more than what you may experience in your everyday life.
- **Benefits:** You may benefit from completing the activity on disclosure or meditation. The knowledge gained from this study will help us create an activity that will help people in recovery from substance use disorders decide whether and how to disclose to, or tell, others about their recovery.
- **Alternatives:** There are no known alternatives available to you other than not taking part in this study.
- **Costs and Compensation:** If you decide to participate there will be no additional cost to you. You will receive a $50 gift card for completing each study visit. You do not have to disclose to receive the second gift card. You may receive another $10 gift card if you complete your second visit within 1 week of when it was scheduled. If you participate over the phone for your second visit, we will text the gift card to you.
- **Participation:** Taking part or not in this research study is your decision. You can decide to participate and then change your mind at any point.

Please carefully read the entire document. You can ask any questions you may have before deciding If you want to participate.

You are being invited to participate in a research study. This consent form tells you about the study including its purpose, what you will be asked to do if you decide to take part, and the risks and benefits of being in the study. Please read the information below and ask us any questions you may have before you decide whether or not you want to participate.

PURPOSE OF THE STUDY

The purpose of this study is to test an activity that we developed to help people decide whether and how they may want to disclose to, or tell, others that they are in recovery from substance use disorders. We are going to compare it to another activity focused on meditation. Both activities involve completing a workbook with a researcher from our team. If you choose to participate, you will be randomly assigned to one of these activities, like with a coin flip.

WHO IS BEING ASKED TO PARTICIPATE?

You will be one of approximately 50 participants in this study.

You are being asked to participate because you are:

(1) Thinking about telling at least one person about your substance use disorder history, treatment or recovery within the next month,
(2) Currently receiving treatment for a substance use disorder at Brandywine Counseling & Community Services,
(3) Are 18 or over,
(4) Have access to a phone and can receive text messages; and
(5) Have not received a diagnosis of Bipolar I Disorder or Schizophrenia.

PROCEDURES: WHAT WILL YOU BE ASKED TO DO?

Your participation in this study will involve two visits, with the second visit occurring 1 month after the first visit. The first visit will an hour or less, and the second visit will last 30 minutes or less. The first study visit will happen at Brandywine Counseling & Community Services with one of our research assistants. At this visit, you will be asked to complete an activity focused on *either* (A) disclosure or (B) meditation with a researcher from our team. You will be randomly assigned to the activity, like with a coin flip. You will also be asked to answer several questions out loud, as part of an interview, and in an electronic survey on an iPad. At the second study visit, you will be asked to answer more questions about whether and how you used what you learned in the activity. The second study visit can

happen on the phone. You can skip any question that you do not want to answer. You do not have to disclose as part of this study. Whether or not you disclose is your choice.

WHAT ARE POSSIBLE RISKS AND DISCOMFORTS?

Possible risks of participating in this research study include a breach of confidentiality, including other people learning that you participated in this study. You may also feel stress or discomfort when thinking about your experiences with disclosure. You are welcome to skip any questions that you don't want to answer. If you do experience emotional distress, a list of available local and national resources is available here: https://earnshawlab.org/study-descriptions-and-requirements/participant-resources/

WHAT ARE POTENTIAL BENEFITS FROM THE STUDY?

You may benefit from completing the activity as part of this study. The activity may either (A) help you decide whether and how you want to disclose to, or tell, someone that you are in recovery from a substance use disorder or (B) help you learn about meditation. Also, some people may enjoy the opportunity to share their experiences or learn about the research process. The knowledge gained from this study will contribute to the creation of an activity that will help people in recovery from substance use disorders decide whether and how to disclose their recovery to others. This may reduce stress related to disclosures and help people gain social support from others, which may help with recovery.

NEW FINDINGS THAT COULD AFFECT YOUR PARTICIPATION

During the course of this study, we may learn new important information. This may include information that could cause you to change your mind about participating in the study. If any new important information becomes available while you are a participant, we will let you know.

CONFIDENTIALITY: WHO MAY KNOW THAT YOU PARTICIPATED IN THIS RESEARCH?

Your study data will be handled as confidentially as possible. If results of this study are published or presented, individual names and other personally identifiable information will not be used. The research team will keep information learned about you confidential to the fullest extent possible. We will store all electronic data on a password-protected computer and all paper materials in a locked cabinet within a locked office. Your name will not be associated with your data, including your responses to the survey or what you say during the interview. If the results of this study are published or presented, individual names and other personally identifiable information will not be used.

We will record the interviews so that we can go back later and learn from what you said. Audio files will be transcribed, or written out, by Mulberry Studio, which is a service based in Boston that maintains a strict confidentiality and privacy policy (see more here: http://mulberrystudio.com/privacy-confidentiality/). After these

audio files have been transcribed, we will destroy the original audio files so that there are no recordings of your voice. Your name will not be included in the transcriptions.

We will keep your study data as confidential as possible, with the exception of certain information that we must report for legal or ethical reasons, such as child abuse, or intent to hurt yourself or others. If required, your records may be inspected by authorized personnel in the following groups and agencies: the University of Delaware Institutional Review Board.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. *Exceptions*: A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing certain information about you for legal or ethical reasons. For example, we will report information about child abuse, or intent to hurt yourself or others. If an insurer, employer, or other person obtains your written consent to receive research information, we cannot use the Certificate to withhold that information. In addition, the Certificate may not be used to withhold information from the federal government needed for auditing or evaluating federally funded projects or information needed by the FDA, e.g., for quality assurance or data analysis.

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

HIPAA AUTHORIZATION

State and federal privacy laws protect your Protected Health Information (PHI). These laws say that, in most cases, your health care provider can release your PHI for the purpose of conducting research only if you give permission by signing an Authorization.

If you agree to participate in the research study, the research team will need to collect and use your PHI. To allow your health care provider to share your PHI with the research team, your approval is required. Signing this Authorization is completely voluntary. However, if you do not sign this Authorization, then you may not participate in the research study.

Who May Disclose and Who may Use and/or Receive my PHI?

By signing this document, you are hereby permitting ***Brandywine Counseling & Community Services*** to disclose the PHI described in this Authorization to the research team involved in this project.

Once your PHI is shared with these persons, you understand that the PHI may no longer be protected by federal or state privacy laws.

What PHI Will Be Disclosed and Used, and for What Purpose?

The following PHI may be disclosed to, collected by, used by and shared with those listed above to better understand how aspects of relationships affect people's health and wellbeing: Medication access, laboratory/diagnostic tests (urine tests), psychological testing relevant to your substance use history and treatment only, and discharge status.

This Authorization will expire at the conclusion of the research study. You may cancel this Authorization at any time before, during, or after your participation in this study by giving a written request with your signature on it to the Principal Investigator at *earnshaw@udel.edu*. If you cancel this Authorization, your PHI obtained before that date may still be used for this research study.

I hereby authorize the disclosure and use of *my Personal Health Information :*
_____*'s Protected Health Information*.
Name of research subject if not the person signing

_____ _____

Signature of Patient or Authorized Representative Date

Printed Name of Person Signing: _____
Relationship to Patient: _____

FOLLOW-UP AUTHORIZATION

This study involves two visits, with the second visit occurring one month after the first visit. After the first visit, we would like to contact you to remind you about the second visit. As part of the study, we will ask you to fill out a **locator form**. This form will include your phone number, email address, mailing address, and Facebook name. We will also ask you to give us the names and phone numbers of several people or agencies that you regularly see. We will contact these people or agencies only if we cannot directly reach you.

When we contact you and the people or agencies listed on your locator form, we will say that we are part of a research study titled "UDisclose." We will never share that the research study is for people in recovery, and we will never share that you are in recovery.

I hereby authorize the study team to ***contact myself and the persons or agencies listed on my locator form***.

Name of research subject if not the person signing

_____ _____

Signature of Participant or Authorized Representative Date

Printed Name of Person Signing: _____

Relationship to Participant: _____

COSTS AND COMPENSATION

There are no costs associated with participating in this study.

You will receive a $50 gift card for completing each study visit. You do not have to disclose to receive the second gift card. You may receive another $10 gift card if you complete your second visit within 1 week of when it was scheduled. For any study visits completed by phone, we will text your gift certificate to you.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is your decision. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide later not to participate, or if you decide to stop taking part in the research, there will be no penalty or loss of benefits to which you are otherwise entitled.

Your decision to stop participation, or not to participate, will not influence current or future relationships with the University of Delaware or Brandywine Counseling & Community Services.

INSTITUTIONAL REVIEW BOARD

This research study has been reviewed and approved by the University of Delaware Institutional Review Board (UD IRB), which is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans. If you have any questions or concerns about your rights as a research participant, you may contact the UD IRB at hsrb-research@udel.edu or (302) 831-2137.

CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues related to this research study you may contact the Principal Investigator, Dr. Valerie Earnshaw, at (302) 831-4772 or Earnshaw@udel.edu.

CONSENT TO PARTICIPATE IN THE RESEARCH STUDY:

I have read and understood the information in this form and I agree to participate in the study. I am 18 years of age or older. I have been given the opportunity to ask any questions I had and those questions have been answered to my satisfaction. I understand that I will be given a copy of this form for my records.

_____	_____	_____
Printed Name of Participant (PRINTED NAME)	Signature of Participant (SIGNATURE)	Date
_____	_____	_____
Person Obtaining Consent (PRINTED NAME)	Person Obtaining Consent (SIGNATURE)	Date

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OPTIONAL CONSENT TO BE CONTACTED FOR FUTURE STUDIES:

Do we have your permission to contact you regarding participation in future studies? If you agree to being contacted in the future, we will keep your contact information. Please write your initials next to your preferred choice.

_____ YES _____ NO
