**INFORMED CONSENT TO PARTICIPATE IN RESEARCH**

The following information describes the research study in which you are being asked to participate. You must be 18 years or older in order to participate. Please read the below information carefully and take whatever time is necessary to make your decision. If you have any questions about the study that you would like answered before you decide, please feel free to ask. You should feel fully informed before making your decision. If you decide that you would like to participate in this research study, you will be asked to sign this document and you will be given a copy.

**TITLE OF RESEARCH STUDY:**

**PRINCIPAL INVESTIGATOR: *[Name, department, institutional affiliation]***

**CO-INVESTIGATOR: *[name, department, institutional affiliation]***

**PURPOSE OF RESEARCH:**

The purpose of this research study is to learn more about ***[describe the purpose of the study in lay terms that will be understandable to the potential participants. For a general audience, readability should be at the sixth to eighth grade reading level].*** You are being invited to participate in this study because ***[describe reasons for asking these individuals to participate].***

**RESEARCH PROCEDURES:**

If you decide to volunteer for this research study, you will be asked to ***[describe the step-by-step activities chronologically in which the participant will be involved during and after the study. The following items must be included in this section]****:*

* ***[The length of time a participant will be expected to commit*** *(e.g., You will be asked to complete two interviews at two week intervals and each interview will last approximately 20 minutes).*
* ***A description of the types of questions that will be asked; topics that will be covered; and data that will be collected through surveys, measures, questionnaires, school records, medical records, etc.*** *(e.g., During the interview you will be asked about your experiences with depression and anxiety; The measures will ask about your responses to different levels of stress; The questionnaire will ask about your use of social networks, etc).*
* ***A description of******where and when the participants can expect to complete study procedures and with whom they will interact*** *(e.g., For your first visit one week from today you will be asked to meet a research assistant at Suffolk University’s Donahue Building).*
* ***A description of******any observations, audio or tape recordings that will be made*** *(e.g., Your interview will be audiotaped and transcribed; Written notes will be taken during the interview).* ***Participants should be made aware if agreement to audio or video-taping is a condition for participation. A separate consent to audio or videotape is to be used when only a segment of the research involves audio or video-taping.***
* ***A clear definition of which procedures are being done as part of the research and which are standard procedures*** *(e.g., The school sponsored writing workshop you are attending is not part of the research study. This research only seeks to collect information that results from the writing workshop and to analyze it to better understand whether this teaching method is effective).*
* ***A clear explanation about the study design*** *(e.g., You will be randomly assigned to a control group or an experimental group by [describe the randomization process]. Neither you nor the investigator can choose the group you will be in. You will have an equal chance of being placed in either group).*
* ***Consider numbering the study procedures if they are extensive.]***

**RISK AND/OR DISCOMFORTS:**

There are no known risks. It is not expected that you will experience any risks and/or discomforts by participating in this research study that are any greater than those normally experienced in everyday life.

***OR***

There are some risks and/or discomforts that you may experience by participating in this study. These risks and/or discomforts may include ***[Describe any risks or discomforts*** *(e.g., boredom or traveling inconveniences and costs)* ***that are reasonably foreseeable and are the result of the study procedures. This includes risks that may result in physical, psychological, legal, social or economic harm, as well as breach of privacy and confidentiality.***

***If there is a possibility that unforeseeable risks exists this must be stated*** *(e.g.,There may be uncommon or unknown risks that are associated with this study. If you experience any adverse effects related to the study that were not anticipated or described in this form you should report these experiences to the investigators.)****]***

***Describe the measures taken to minimize these risks and/or discomforts.***

**BENEFITS:**

You may directly benefit from participating in this study. These benefits include ***[Describe any***

***reasonably expected direct benefits that the individual participants will receive. Compensation for***

***participation is not considered a benefit.]***

***OR***

There are no direct benefits to you from being in this study. It is possible that others may benefit from this study by ***[Describe how the general population may benefit*** *(e.g. Educating faculty and staff at other colleges and universities on the best way to assist students suffering mental health issue may lead to improved mental health care; Your participation will help the investigators learn more about the effectiveness of this treatment model for treating depression in young adults).****]***

***For Research involving Suffolk Students Include:*** Your grades will not benefit as a result of your participation in this research study. It is possible that your professor will know if participate in this study; however, there are safeguards in place to protect your confidentiality and to prevent your professor from knowing if you chose *not* to participate in this study. ***[Describe what these safeguards may be]***

***For Research involving Prisoners Include:*** Your housing, correctional program assignments or parole circumstances will not benefit from your participation in this study and you will not be punished or hurt in any way if you choose not to participate. Your release will not be impacted in any way from participating in this study.

**ALTERNATIVES:**

The alternative is not to participate in this study. ***[Most studies will not have relevant alternatives to study procedures. However, there may be circumstance where this may apply in a social behavioral setting*** *(e.g., Your alternative is to attend the school sponsored writing workshop without providing consent for the researchers to collect and record the information resulting from the workshop; There may be alternative methods for dealing with your depression or anxiety, for example, you can go to the Counseling Center at Suffolk University to receive the standard care for treating anxiety or depression****.]***

***For Research with PSYCH 114 Students Include:***You do not have to participate in this research study to receive the required research credits. There are alternative methods of obtaining such credits.

**PRIVACY AND CONFIDENTIALITY:**

Your privacy will be protected by ***[Describe in detail how participant privacy will be protected*** *(e.g., All interviews will be conducted in a private room, only you and the researchers will be present at all times; You will be asked not to use your real name during the focus group discussions; In describing real life events or experiences, you will be asked to refrain from using places or individuals’ real names. Instead you can say my “mother”, ”father”, “school” or “store”)****.]***

The confidentiality *[or anonymity if applicable]* of the information obtained will be maintained by ***[Describe in detail how participant confidentiality or anonymity will be protected. Describe the extent to which confidentiality of research records identifying the participant will be maintained and the limits of such confidentiality. Specifically, describe in detail:***

* ***Where and how the records will be kept;***
* ***Who will have access to these records;***
* ***When identifying information is replaced by a code, how the linkage between two items will be maintained, for how long and by whom;***
* ***If coding information, whether or not there is any likelihood that subjects can be re-identified simply by the combination of pieces of de-identified information collected*** *(e.g., it is possible the combination of all the de-identified data such as age, country of origin, major in college, marital status, race, gender may allow someone to know the data pertains to a specific individual.)*
* ***For online research, describe whether IP addresses or e-mails will be retained and the extent of online data security*** *(e.g., Your data is collected via a secured encrypted network; The IP address tracking system has been disabled for the purpose of this research study; The online survey provider may keep your e-mail address for their records but will not disclose it to any third party.)* ***If using a third party website, you may want to include a link to the websites privacy policy***
* ***If a Certificate of Confidentiality is in place, describe the limits of the certificate’s protection.***
* ***If conducting video or audio recording, describe what will be done with the tapes, plans for storage during use and what will be done after transcription*** *(e.g., The audio tapes will be transcribed and immediately destroyed; The video recordings will be downloaded into a password protected computer and deleted from the video camera)****.***
* ***If conducting focus groups or group interviews, describe the measures taken, if any, to protect other’s disclosure of private information*** *(e.g., You will be asked to refrain from using yours or other’s real names in talking about your experience. You will be asked to turn off your cell phone camera and refrain from taking pictures or audio and video recording. This will prevent others in the focus group from inadvertently disclosing private information.)****]***

**COMPENSATION:**

You will not receive any money or other form of compensation for participating in this research study.

***OR***

To compensate you for your time and participation, you will receive ***[Describe the monetary or other compensation provided to participants. Include such details as at whether compensation will be pro-rated in the event a subject withdraws from the study and how payments will be distributed. If additional private information is collected for the purpose of compensating participants, this must be clearly stated and a description of how this information will be protected must be included.]***

**VOLUNTARY NATURE OF PARTICIPATION/ RIGHT TO WITHDRAW:**

Participating in this research is voluntary. You have the right to refuse to participate. If you decide to participate, you may withdraw your consent at any time and any information collected from you will be destroyed. Your withdrawal will not result in any penalty or loss of benefits and/or services that you might be entitled to receive. The investigator may also determine that it is in your best interest to discontinue your participation at any time.

***For Research Involving Suffolk Students****:* Your withdrawal or refusal to participate in this research study will not adversely affect your grade or standing at Suffolk University.

**CONTACT INFORMATION:**

If you have any questions about this study including the purpose, procedures, and/or risks and benefits you may contact ***[Include the principal investigators phone number and e-mail address and mailing as well as that of any co-investigator who is assigned]***

If you have questions about your rights as a research participant or to report any concerns you may have please contact Suffolk University’s Institutional Review Board (IRB) at 617-725-4169.

**CONSENT:**

I have read the information in this document and I am aware of the risks and benefits involved. I have been given a chance to ask questions and enough time to decide whether to participate. By signing below I am voluntarily agreeing to participate in this research study.

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Signature of Participant Date

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Printed Name of Participant

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Signature of Person Obtaining Consent Date

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Printed Name of Person Obtaining Consent

IRB APPROVAL

STAMP

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