Millersville University of Pennsylvania Institutional Review Board for the Protection of Human Subjects

Human Subjects Review Protocol

NOTE: <u>Download and save this form to your desktop before adding information</u>.

1.	Princ	cipal Investigator:				
	Name:	:				
			Department:			
	Offic	ce Phone:	E-Mail Address:			
	Addr	ress:				
	Posit	tion:				
		udent researcher: Are you a graduation	luate or undergraduate student; expected date of			
	Revi	iewed by: (if student)Department Co	mmitteeFaculty Advisor Date			
2.	Co-ir	nvestigator (or thesis committee chair, adv	visor; use of a second sheet for any additional names):			
	Name:		Department:			
	Offic	ce Phone:	E-Mail Address:			
	Addr	ress:				
	Posit	tion:				
3.	Proje	ect Title:				
	Dates of	during which project will be conducted	I (MM/DD/YYYY): To:			
4.	А.	Project Funding Source: Check as m	any as apply:			
		MU Grant Non-funded	me:			
	B. If grant funded, application deadline or date of transmittal					
		Please submit one copy of grant pro	posal as soon as it is available.			

5. <u>Protected Populations and Sensitive Subjects:</u> If <u>any</u> Human Subjects from the following list would be involved in the proposed activity, place an X next to the category.

Minors	Pregnant Women	Test subjects for new
Fetuses	Illegal behavior	drugs or clinical
Abortuses	Mentally disabled	devices
Incarcerated	Educationally or economica	lly disadvantaged persons

6. <u>Nature of Risk</u>. In your judgment, does your research involve more than minimal risk? "Minimal risk" means that the risk of harm anticipated in the proposed research is not more likely than those risks encountered in daily life, or during routine physical or psychological examinations/tests.

Yes No

7. Additions to or changes in procedures involving human subjects as well as any problems connected with the use of human subjects once the project has begun must be brought to the attention of the IRB.

By typing my name below, I agree to provide whatever surveillance is necessary to ensure that the rights and welfare of the human subjects are properly protected. I understand that I cannot initiate any research with human subjects before I have received approval/or complied with all contingencies made in connection with the approval. I understand that as the principal investigator I am ultimately responsible for the welfare and protection of human subjects and will carry out the project as approved.

I have completed CITI Training.

I have NOT COMPLETED CITI Training. As of January 1, 2015, this is a mandatory requirement. If you have not completed training, please go to www.citiprogram.org, login with your Millersville username and password, and complete the on-line program.

Name of Principal Investigator/Program Director

8. Approval by Faculty Sponsor (required for **all** students): By typing my name below, I affirm the completeness and accuracy of this application, and I accept the responsibility for the conduct of this research and supervision of human subjects as required by law.

Faculty Sponsor Name

The following pages include directions for completing your IRB protocol. Please include information addressing each of the points below, including informed consent. Once you have completed the protocol, please using the buttons at the bottom of this form submit your document. If you need assistance, please contact Rene Munoz by email or by phone at ext. 4457.

Date

Date

A. Project Purpose and Background

<u>Purpose of the study</u> – Please state what the study will accomplish. 3,000 character limit.

B. <u>Background</u> - Briefly state the background of the study, including references when appropriate, and identify the main questions the current study is intended to address. 3,000 character limit.

- C. <u>Characteristics of the Subject Population</u> Please provide the following information:
 - a. Vulnerable Subjects If vulnerable subjects will be included (children, pregnant women, prisoners, mentally ill) provide justification of the need to use these subjects in research. Enter N/A if no vulnerable subjects will be included.

b. <u>Exclusion Criteria</u> - What are the specific exclusion criteria? Clear rationale should be provided for the exclusion of any particular population group, unless the title of the study reflects the restricted population range.

c. <u>Inclusion Criteria</u>-What are the specific inclusion criteria?

d. <u>Number</u> – What is the estimated number of subjects?

e. <u>Gender</u> – What is the gender of the subjects? If there is a restriction, provide the rationale.

f. <u>Age Range</u> – What is the age range and why was it chosen?

D. INFORMED CONSENT

Please include a copy of the informed consent you will distribute to study participants with this protocol.

a. <u>Potential Risk</u> – Identify the potential risks of the study. Specify types and levels of risk.

b. <u>Protection Against Risks</u> - For all studies involving greater than minimal risk, specify the procedures for preventing or minimizing any potential risks.

c. <u>Potential Benefits</u> - Describe any potential non-monetary benefits of the study, both for subjects and for society in general.

E. <u>METHODS AND PROCEDURES</u>

a. Method of Subject Selection - Describe the study's method(s) of identification and recruitment of prospective subjects. <u>Provide a copy of any planned</u> <u>advertisements.</u>

b. Study Site – State the location(s) where the study will be conducted. <u>Include</u> <u>letters of approval to conduct the study from all non-MU sites.</u> c. <u>Methods and Procedures Applied to Human Subjects</u> - Describe in detail the study design and all procedures (sequentially) to be applied to subjects. <u>Attach</u> <u>copies of any instruments to be used, such as surveys, rating scales, or</u> <u>questionnaires.</u>

d. <u>Compensation for Participation</u> - Describe any monetary or other forms of compensation which will be provided to subjects, and any conditions which must be fulfilled to receive compensation.

e. <u>Alternatives to Participation</u> - Describe any alternatives to participation in the study which might be advantageous to the subject. If the subjects are to receive academic credit for research participation, describe the alternatives available to earn equivalent academic credit.

f. <u>Information Withheld</u> - Identify the nature of any information to be purposely withheld from subjects, and provide justification for the nondisclosure.

g. <u>Debriefing</u> - Describe the procedure for post-study debriefing of subjects.

h. <u>Confidentiality of Data</u> - Describe explicitly how confidentiality of data will be maintained.

If any information with subject identifiers will be released, specify the recipients. Include a statement that all data will be retained for at least three years in compliance with federal regulations.

Appendix A

Demographics Sheet

Last 4 Digits of your Millersville ID (M#):

Instructions: Please mark or fill in the answer that best describes you.

- Gender
 - o Male
 - Female
 - Other: _____
- Age: _____
- Race:
 - White
 - Hispanic / Latino
 - $\circ \quad Black \, / \, African \, American$
 - Native American
 - o Asian
 - Pacific Islanders
 - Other: _____
- Major:_____
- Minor:_____
- Class level:
 - Freshman (0-30 Credits)
 - Sophomore(30.5-60 Credits)
 - o Junior (60.5-90 Credits)
 - Senior(90.5-120 Credits)

Appendix B Questionnaire Sheet

Last 4 Digits of your Millersville ID (M#):

Instructions: Please read through each item carefully and put a check mark in the box corresponding with the level of agreement that most applies to you.

*SSOSH Scale items are highlighted for the sake of this protocol. There will be no formatting difference between items when this questionnaire is administered to participants.

	1	2	3	4	5
	Strongly Agree	Agree	Disagree and Agree Equally	Disagree	Strongly Disagree
I would feel inadequate if I went to a therapist for psychological help.*					
Having to ask my parents for money would make me feel terrible about myself.					
My self-confidence would NOT be threatened if I sought professional help.*					
Seeking out a friend for studying help would make me feel stupid.					
Seeking psychological help would make me feel less intelligent.*					
I would be embarrassed to share financial burdens with my family.					
My self-esteem would increase if I talked to a therapist.*					
I would see not being able to handle my academic problems as a failure.					
My view of myself would not change just because I made the choice to see a therapist.*					

	1	2	3	4	5
	Strongly Agree	Agree	Disagree and Agree Equally	Disagree	Strongly Disagree
I would NOT be ashamed if I needed my parents' help with filing my taxes.					
It would make me feel inferior to ask a therapist for help. *					
I would have less self- confidence if I needed a peer-tutor to pass a class.					
I would feel okay about myself if I made the choice to seek professional help.*					
If I went to a therapist, I would be less satisfied with myself.*					
I would be embarrassed to go to a friend for academic help.					
My self-confidence would remain the same if I sought help for a problem I could not solve.*					
My self-esteem would NOT drop if I needed financial help from family.					
I would feel worse about myself if I could not solve my own problems.*					

Appendix C

Informed Consent Form

You are being asked to participate in a study conducted by student researcher Erin Logue, under the supervision of her mentor, Dr. Thyrum. This study is part of Erin Logue's Millersville University Psychology Department Honors Program requirements. Please read the following carefully and ask any questions you have before signing. Signing your name and the date at the bottom of the page indicates that you understand the information provided below and agree to participate.

Purpose, Procedures, and Risks: This study seeks to examine students' reactions to various videos. On the first day of the study, all you will be asked to do is to complete a questionnaire. Approximately a week later, you will be asked to watch a video, and complete the same questionnaire again. There are no known risks associated with participation in this study

<u>Compensation, Refusal, and Withdrawal:</u> All participants will have the opportunity to enter their name into a random drawing to win a gift card. Participation is voluntary, and can be terminated at any time with no negative consequences.

Confidentiality: Your confidentiality will be maintained throughout the study by the use of the last 4 digits of your Millersville ID (M#) as a participant ID, rather than using identifying information such as your name or full ID. All questionnaires will be kept in a locked filing cabinet in a locked office in Byerly Hall for the duration of the study. In compliance with Federal law, they will be kept for three years, at which time any documents with identifying information will be destroyed.

Age: All participants must be over the age of 18.

<u>**Contact</u>**: If you have any questions, comments, or concerns before, during, or after the study, please contact Erin Logue or Dr. Thyrum. They will be more than happy to answer any questions and to provide any additional information.</u>

<u>Responsible Parties:</u> This study has been approved by the Millersville University of Pennsylvania Institutional Review Board. Dr. René Muñoz, Director of Sponsored Projects and Research Administration, can be contacted with any questions at either (717) 871-4457 or (717) 871-4146, or at rene.munoz@millersville.edu.

Participant Signature

Date

Student Researcher Millersville University Psychology Department Dr. Elizabeth Thyrum Honors Program Mentor Millersville University Psychology Department Elizabeth.Thyrum@millersville.edu Byerly Hall 120 717-871-7278

Appendix D

Debriefing Form

Thank you for participating in the study, your contribution is highly valued and appreciated.

The purpose of the study was to determine whether celebrity advocates or non-famous individuals would be more effective in reducing mental illness self-stigma in college students. This is different than the purpose of the study described to you at the beginning of the study. Research has shown that participants often feel there is a favorable answer on questionnaires focused on social topics such as stigma, and choose those answers even when they actually feel that a different answer better reflects their thoughts. For this reason, all participants were told the study focused on students' reactions to various videos.

There are two types of stigma relevant to mental illness: Public and self. Public stigma is the negative attitudes and behaviors held towards someone with a mental illness, such as believing they have a character flaw because of the illness, or failing to give them deserved job placements, housing, or medical care. Self-stigma, which is the focus of this study, is the internalized version of this that can cause the individual with the mental illness to view themselves negatively because of the illness, and fail to seek treatment or help.

Three different interventions (unrelated control, celebrity advocate, and non-famous videos) were provided to the three groups, meaning you will have only been given one. The answers to the questionnaire for each group will be compared to determine the overall effectiveness of the interventions. All answers provided by participants are completely confidential, with no way for the researcher or anyone else to connect participant answers to the participant identification. In compliance with federal law, all questionnaires will be saved for 3 years, at which time all documents containing any identifying information will be destroyed.

If you are uncomfortable about anything that happened while participating in the study, or have any questions or comments, I urge you to contact me either in person, or by e-mail. You can also contact my mentor, Dr. Thyrum, with any questions, comments, or concerns.

If you believe you or someone you know may be in need of help in dealing with a mental illness or mental health, please contact the Millersville Counseling Services by going to the Center for Counseling and Human Development, located on the 3rd floor of Lyle Hall, or by calling 717-871-7821.

Again, thank you for participating in the study! Your contribution will help us to understand how to most effectively reduce mental illness stigma in college students

Student Researcher Millersville University Psychology Department Dr. Elizabeth Thyrum Honors Program Mentor Millersville University Psychology Department Elizabeth.Thyrum@millersville.edu Byerly Hall 120 717-871-727