University of Southern California
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INFORMED ASSENT/CONSENT FOR RESEARCH

Study Title: Proud & Empowered Intervention Efficacy
Principal Investigator: Harmony Rhoades, PhD
Department: Suzanne Dworak-Peck School of Social Work

INTRODUCTION

We invite you to take part in a research study. Please take as much time as you need to read the assent/consent form. You may want to discuss it with your family or friends. If you find any of the language difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form. A copy of the signed form can be provided to you for your records.

PURPOSE

The purpose of this study is to determine if the Proud & Empowered Intervention for LGBTQ+ youth impacts mental health among LGBTQ+ youth. You are invited as a possible participant because you identify as LGBTQ+ and attend a school selected to be part of this study. About 450 participants across all schools will take part in this study. This research is being funded by the National Institute of Minority Health and Health Disparities.

PROCEDURES

If you decide to take part in this study, you will either participate in the Proud & Empowered intervention and complete three surveys, or only complete three surveys. This is a 50/50 chance and depends on if your school is selected as an intervention school or control school.

We will ask you to complete three surveys as part of this study: at the beginning of the school year, at 10 weeks after the first survey, and at the end of the school year. The survey will ask you to respond to questions about sensitive information and some personal experiences at home, within school, within community and within your relationships. You will also be asked to respond to questions about your mental health, different behaviors, and drug use. All surveys will take about 30 minutes to complete. You will create a unique code that will be used to link to your survey responses so that no one at the school will know how you answer.

If you are in a school selected to receive the intervention, you will participate in an intervention group for about 45 minutes once a week for 10 weeks during the semester. In this group we'll talk about specific issues that you and other LGBTQ+ youth might be facing and ways to deal with those issues, including stress and coping skills, disclosure, family, school-related stress, peers and friendship, race/ethnicity and social justice, and history of the LGBTQ+ community.

The intervention sessions will take place at school during school hours, either during homeroom/advisory or during class. If participation is during class, you will need to miss class to participate in the sessions. We will schedule these sessions at different times and days each week so that you will not miss the same class every week.

RISKS AND DISCOMFORTS

Survey: The survey will ask you to respond to questions about sensitive information and some personal experiences at home, within school, within community and within your relationships. You will also be asked to respond to questions about your mental health, different behaviors, and drug use. Some of these questions may make you feel uncomfortable or become upset. If this happens, we have listed some resources within the survey that you can contact and who can provide you with support. You may also skip or stop answering any questions that make you uncomfortable.

Breach of Confidentiality: You are providing highly sensitive, personal information in this study. If people not connected with the study learn this information, you could have problems getting a new job, keeping your current job, finding housing, or getting insurance (health, disability, or life insurance). In highly unlikely situations, you could be charged with a crime.

BENEFITS

Possible benefits to you for taking part in this study may include better understanding how to cope with stress and connecting with supportive students and staff at your school. Possible benefits to others may be improving the overall climate at your school, and increasing knowledge about what interventions help LGBTQ+ young people.

PRIVACY/CONFIDENTIALITY

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. Efforts will be made to limit the use and disclosure of your personal information, including information obtained by this research study, to people who are required to review this information. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name.

The University of Southern California's Institutional Review Board (IRB) and Human Subjects Protections Program (HSPP) may review your records. Organizations that may also inspect and copy your information include the National Institute on Minority Health and Health Disparities.

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 at any time.

The investigators are required to report certain cases with the potential of serious harm to you, or others, such as suicidality or child abuse, to the appropriate authorities.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

ALTERNATIVES:

The alternative to participating in this study is to not participate in this study.

PAYMENTS/COMPENSATION

You will be compensated for taking three surveys as part of this study: at the beginning of the school year, at 10 weeks after the first survey, and at the end of the school year. You will get a $20 gift card for the first survey, $25 for the second, and $30 for the last one, for a total of $75 in gift cards if you complete all three surveys. You will be paid separately for each survey completed and do not need to complete all of the surveys in order to receive payment.

COST

There is no cost to you for participating in this study. Research costs are paid by the sponsor or funding agency.

INJURY

If you are injured as a direct result of research procedures, you will receive medical treatment; however, you or your insurance will be responsible for the cost. The

University of Southern California does not provide any monetary compensation for injury.

NEW INFORMATION

We will tell you about any new information that may affect your health, welfare, or willingness to stay in the research.

VOLUNTARY PARTICIPATION

It is your choice whether to participate. If you choose to participate, you may change your mind and leave the study at any time. If you decide not to participate, or choose to end your participation in this study, you will not be penalized or lose any benefits that you are otherwise entitled to.

WITHDRAWAL FROM STUDY INSTRUCTIONS

You can leave the research at any time by informing the study facilitator or your school counselor. Your decisions will not be held against you.

If you withdraw from the study, you will no longer be able to participate in the study. No new information will be collected about you or from you by the study team. Your withdrawal has no effect on the lawfulness of the data processing that occurred prior to your withdrawal.

CONTACT INFORMATION

If you have questions, concerns, complaints, or think the research has hurt you, talk to the study investigator, Harmony Rhoades, PhD at hrhoades@usc.edu.

This research has been reviewed by the USC Institutional Review Board (IRB). The IRB is a research review board that reviews and monitors research studies to protect the rights and welfare of research participants. Contact the IRB if you have questions about your rights as a research participant or you have complaints about the research. You may contact the IRB at (323) 442-0114 or by email at irb@usc.edu.

STATEMENT OF ASSENT/CONSENT

Do you have any questions? Now that you've heard all that is involved in this study, and have had any questions answered, do you agree to participate?

If agree, read: Great, let's get started.

If decline: inform participant that they will not be able to participate in group and work with school liaison to remove them from the participation charter.