Official Title: Organization-level Youth Engagement Approach for Substance Misuse Prevention

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Wake Forest®
School of Medicine

Department/Section of *Family and Community Medicine*

Organization-level Youth Engagement Approach for Substance Misuse Prevention
Informed Consent Form to Participate in Research
Parissa J. Ballard, PhD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to develop an organization-level youth engagement (**YE**) approach (**YEA**) to substance misuse prevention and to implement it with community-based organizations to test feasibility, acceptability, and effectiveness. YE is an approach to prevention that refers to prevention organizations effectively engaging youth as leaders or partners in planning, tailoring, implementing, and/or evaluating prevention programming. This study will involve four organizations: two will be randomized (50/50 chance) to implement the YEA, and two will serve as comparison groups. If your organization is selected for the intervention group, we ask that 2-3 organizational leaders/staff attend 7 virtual sessions with the study team over the next 6 months (approximately). If your organization is selected as a comparison group, YEA materials will be made available to you after the study is completed.

Organizations in both the intervention and comparison groups will provide data to the study. This involves 2-3 leaders/staff completing a survey (~20 minutes) and an interview (30 – 60 minutes). Interviews and check-ins may be in-person, by telephone, or by video call, and may be individually or in groups. For comparison groups, interviews topics will include questions about your usual prevention efforts. For intervention groups, interview topics will include questions about your usual prevention efforts as well as questions about your experiences with the incorporating the YEA into prevention efforts. We will audio-record the interviews so that we can put your words to paper. You may request that the audio recording be stopped at any time (although your right to stop the recording or withdraw consent may be more limited in a group interview).

Organizations in the intervention group will also distribute an information sheet (similar to this one) and an online survey link to youth/young adults who you end up working with in the course of study participation. We will provide the information sheet and the survey. Youth/young adults will complete the surveys two times (pre- and post-intervention). Each survey should require around 20 minutes. We will also invite a subset of youth who participate in the survey to complete an audio-recorded interview with our team.

You are invited to be in this study because you are a leader or staff of a community-based prevention organization interested in the YEA.

All research studies involve some risks. A risk to this study that you should be aware of is study staff not protecting your private information. Your organization may benefit from implementing

the YEA (for the intervention groups) or accessing materials after the study (for the comparison groups). You may not directly benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Parissa J. Ballard, PhD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, her contact information is [redacted].

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

How Many People Will Take Part in the Study?

We will interview and/or survey approximately three leaders/staff in each participating organization and up to 60 youth in each of the two organizations who implement the YEA (the intervention organizations), for a total of up to 15 leaders/staff and up to 120 youth/young adults (up to 135 people overall).

What Are the Risks of the Study?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

There is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

As part of this study, you will be asked questions about substance misuse prevention efforts. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

Are There Benefits to Taking Part in the Study?

You are not expected to receive any direct benefit from taking part in this research study. We hope that your organization will benefit from implementing YEA (for the intervention group) or receiving the YEA materials the study ends (for the comparison group) and that the information learned from this study will benefit other people in the future.

WHAT ARE THE COSTS?
There is no cost to participation.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?
The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

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, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is 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. 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.

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

WILL YOU BE PAID FOR PARTICIPATING?
Your organization will be paid $250 for participation in the study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?
You may choose not to take part or you may leave the study at any time. If you decide to stop participating in the study, we encourage you to talk to the investigator or study staff. The investigator also has the right to stop your participation in the study at any time. Information about you may be removed from the study data and could be used for future research or shared with other researchers without additional consent from you.

By continuing, I agree to take part in this study. I authorize the use and disclosure of my personal information as described in this consent and authorization form. I have had a chance to ask

questions about being in this study and have those questions answered. By taking part in the study, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.