Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Dr. Jordan Nelon, PhD, MPH
Study Title: Tennessee Youth Prepared for Success
Organization: Centerstone Research Institute

IRB APPROVED
AS MODIFIED
Jul 20, 2023

This informed consent document applies to Parent or Guardian

TITLE: Tennessee Youth Prepared for Success

PROTOCOL NO.: None
WCG IRB Protocol #20225947

SPONSOR: Centerstone Research Institute

INVESTIGATOR: Jordan L. Nelon, PhD, MPH
44 Vantage Way Ste 400
Nashville, Tennessee 37228
United States

STUDY-RELATED PHONE NUMBER(S): **(**214) 733-2946 (24 hours)

The following information is provided to inform you about a research study in which your youth has been invited to participate. The study will begin within the next school year and last for 12 months. The decision to let your youth participate, or not participate, is completely voluntary. If you choose not to permit your youth to participate, their involvement in the *Tennessee Youth Prepared for Success* program (Be In Charge curriculum or Adolescent Health Curriculum*)* or other rights will *not* otherwise be affected. Your youth will still be eligible to receive the same experience and education as the other participants; this consent form only pertains to data collection. This consent form will be kept until 2027. If you need a copy, please contact Dr. Jordan Nelon at (214) 733-2946.

Purpose: *Tennessee Youth Prepared for Success* is a randomized control trial funded by the Administration for Children and Families and Family and Youth Services Bureau and is conducted by trained Centerstone Prevention Specialists. Through participating in the program, we hope to develop and test a new curricula specifically for rural teens that meet Family Life Curriculum Standards. Youth can receive two different curricula for youth ages 14 to 19 years old: the Be In Charge curriculum or the Adolescent Health Curriculum. The *Tennessee Youth Prepared for Success* program was designed to increase understanding of the benefits of abstinence and increase motivation to remain abstinent while helping gain/improve skills necessary to reduce risk of teen pregnancy and STIs. The key strategy is to impact attitudes, beliefs, and behaviors by increasing knowledge about the prevention of STIs, HIV, and pregnancy through the provision of medically accurate information concerning the benefits of abstinence with a series of fun and interactive learning experiences (e.g., video clips, interactive workbooks, role-playing, skill-building activities, etc.). The control group will receive the Adolescent Health Curriculum which is designed to navigate youth through the emotional components of adolescence. The responses of all youth participating in this study will help us understand, 1) how relevant the curriculum is (i.e., *do young people like it?*), 2) if it increases knowledge about the benefits of abstinence (*i.e., reduce pregnancy, reduce STIs*), and 3) if information shared during class time can be used in real life situations. Approximately 1,200 youth will be involved in this study from 2022-2025. *Tennessee Youth Prepared for Success* is a Randomized Controlled Trial which means classes will be randomly assigned to one of the curricula. Both groups need to complete all data collection and can receive all incentives.

Description of Study Participation: Your youth will be offered either an abstinence-based teen pregnancy prevention program or an emotional support program facilitated by Centerstone Research Institute at your youth's school. We will ask your youth to complete a survey before and several after they finish the program. The surveys will ask students about their feelings, attitudes, and behaviors related to engaging in sexual activity, their intention to use contraceptive methods, perceived benefits related to delaying sexual initiation, and their knowledge about pregnancy and sexually transmitted infections (STIs). **You or your youth may choose to stop participating in the survey at any time and your youth can *still* participate in the Be In Charge or**

Adolescent Health Curriculum without participating in the research portion. There will be no penalties or loss of benefits to which your youth is otherwise entitled if you or your youth decide not to participate or to withdraw.
Possible inconvenience, discomfort, and/or risk: The potential discomfort of participating in this study is minimal. We have taken multiple steps to protect your youth's privacy. However, in the course of any research study, there are potential risks and some of them are unknown at this time. Your youth may feel discomfort associated with sharing personal feelings, attitudes, and behaviors. The time it takes to complete the survey for the study may be a slight inconvenience to your youth. In order to minimize the discomfort, the survey will take approximately 20 minutes. Should your youth feel uncomfortable, they can skip questions or stop taking the survey at any time. The research & evaluation team will closely follow designated procedures for protection of your youth's confidential data and materials.

Anticipated benefits from this study: The potential benefit to science and humankind that may result from this research study is a better understanding of the effectiveness of prevention programs for youth who are at-risk for teenage pregnancy and sexually transmitted diseases. **Participants will have the opportunity to be compensated for their time in the study. They will receive a $15 gift card at the completion of the posttest, $15 gift card at the completion of a six month survey, and a $20 gift card at the completion of the 12 month survey.**

Alternatives: This research study does not involve treatments or interventions. The only alternative is not to participate.

Compensation in case of study-related injury: Immediate and necessary care will be provided without charge by Centerstone if your youth is injured because of participation in this study. You will not be charged for this care if the injury would not have been expected from standard services or would not have occurred if you were not taking part in this study. However, there is no provision for the costs of further long-term medical care or for monetary compensation for such injury.

Circumstances under which the Principal Investigator may withdraw your youth from study participation: The research staff may stop your youth's participation in the study without your consent or your youth's consent for any reason, including the following: failure to follow the study personnel's instructions regarding study conditions and procedures, any serious adverse event that may require evaluation, or if it is in the best interest of your youth's health and welfare.

What happens if you or your youth chooses to withdraw from the study: If you decide to provide consent for your youth to participate in the study now and later change your mind, you may stop your youth's participation in the study at any time. Participation in this study is voluntary, and you may withdraw your youth without any penalty. Also, your youth may withdraw him or herself without penalty. Your youth will still be able to continue in *Tennessee Youth Prepared for Success* or *Adolescent Health Curriculum* and will not be treated any differently from others in the study.

Confidentiality and privacy: Any information your youth provides for research purposes will be kept completely confidential and private. To help protect confidentiality, all study information will be coded using an identification number rather than a name. A list of the names and identification numbers of participants will be kept separately from the study data in a password protected computer file. Any reports generated from this study will be aggregate data. No information can be reported that would identify any participating individual by name. Information may be shared between research and prevention staff in emergency situations. We will need to disclose information about your youth if federal, state, or local law requires us to do so.

Your youth's information may be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies including the Food and Drug Administration (FDA)
- The Institutional Review Board (IRB) that reviewed this research

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We may publish the results of this research. However, we will keep your youth's name and other identifying information confidential.

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.

Contact information: If you should have any questions, concerns, or complaints about this research study, please feel free to contact the study contact, Dr. Jordan Nelon, at (214) 733-2946 (24 hours) or jordan.nelon@centerstone.org. For additional information about giving consent or your youth's rights as a participant in this study, you may contact WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your youth's rights as a research subject.

Assent Requirement:

- All youth are required to assent
- Youth will sign a separate assent form

STATEMENT BY PARENT OR LEGAL GUARDIAN PERMITTING YOUTH TO PARTICIPATE IN THIS STUDY

I have read this informed consent document. All my questions have been answered, and as parent or legal guardian, and by signing this consent from I freely and voluntarily authorize _____ (youth's name) to become a participant in the research study and participate in the learning opportunity described in this form.

_____ _____
Date Parent or Legal Guardian's Signature

_____
Parent or Legal Guardian's Printed Name

Name of student: _____**Date of Birth**: _____

Student phone number: _____ **Parent phone number**: _____

Student school email: _____ **Student personal email (non-school)**: _____
Note: Contact information will only be used to distribute survey materials.