



COMPONENT 1 INFORMED CONSENT (>18 Youth)

	INFORMED CONSENT AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH	
<p>We try to make this form easy to understand. But it may have words or ideas that are not clear to you. Please ask a member of the study team to explain anything you do not understand. You may take this form home with you to discuss with family or friends before you decide whether to be in this research study.</p>		
Study Title: Stress and Coping Among High School Students (ALACRITY eSToRY R34 #1)		
Your name (Participant):	Today's Date:	
<u>Not including this study</u>, are you taking part in any research now? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Name of Principal Investigator: Margaret Weiss, MD, PhD		
Name of Co-Investigator(s): Eleanor Richards, PhD		
Consent form version date or number: 07/25/23 v5		
Name and telephone number of study contact to call with questions: Margaret Weiss, MD, PHD [617 665 3338]		
CHA IRB Number: CHA-IRB-1190/06/21	Study Sponsor(s): NIMH	

 CHA Cambridge Health Alliance		ASSENT FORM 12 - 17 years old	
Participant's Name :			
Today's Date:			
Home Address:			
Name of Investigator: Margaret Weiss, MD, PhD			
Title of Study: Stress and Coping Among High School Students (ALACRITY eSToRY R34 #1)			

Why am I here?

We want to talk to you and your parents/guardians about a research study. We as researchers hope to help you and others like you, and research is a special way to learn about something new. We hope to learn more about ways to improve mental wellness. We will be using an online research intervention program called COPE2Thrive. You have been invited to be part of this research study because our initial screener indicated that you may benefit from the COPE2Thrive program. Additionally, you are a high schooler in Everett, Somerville, Cambridge, Chelsea, Malden, Winthrop, or Revere

Why is this study being done?

This study is being done to try to find out more about what emotional challenges teenagers are facing now, and whether an online program to improve emotional wellbeing, COPE2Thrive, is helpful.

How many other teenagers will take part in this study?

We hope to have at least 108 students participating in our study.

How long will I be in this study?

If you decide to participate in this study, it will be for up to 12 months.

Remember: You can stop being in the study at any time for any reason. If you decide to stop, we encourage you to talk to one of us first. If you decide to leave the study, we will use the information you have shared up to the time when you want to stop.

What do I have to do if I am in the study?

COMPONENT 2 ASSENT FORM (Version 8)

Your parent or guardian's consent will be needed for you to be in this study. If we are unable to reach your parent/guardian or if they do not consent, you will not be able to participate. If they agree to let you take part, you will complete seven online lessons that take 20-30 minutes each to complete. You will have two months to complete the program. The program teaches strategies to improve coping and well-being. You will be asked to create an account to access the digital intervention. To do so, you will enter your name, email, and create a password for the site. You will also complete questions about how you are doing at three points in time: when you start the program, when you complete the program, and 3 months after completing the program to track your progress. Your parent/guardian will also be asked to answer questions about how they think you are doing at these three times.

The information you give us is confidential. However, if we learn that you are a danger to yourself or others, the law requires us to let your parents/guardians know and get you the help you need. If you tell us that you are being abused or neglected, we are required to inform the Department of Children and Families.

Research staff will be available for assistance each weekday (Monday – Friday) during your time in the study.

What are the risks of taking part in this study?

You may have to answer personal questions about your feelings and behaviors. These might make you feel uncomfortable and may make you aware of any emotional difficulties you have been struggling with. If you are identified by the research team as requiring emergency care, all needed emergency care is available to you, just as it is to the general public. Any needed medical care is available to you at the usual cost. You or your insurance carrier will have to pay for any such medical care.

Cambridge Health Alliance has not set aside any money to pay for a research-related injury or illness. There are no plans to pay for your treatment if treatment is recommended by the research team.

What are the benefits of taking part in this study?

You may find that by joining our study, you can see how your thoughts and emotions change over time. We also hope that the online program teaches you new skills to manage stress.

Will I get paid to be in this study?

Yes! You will be paid for your time with a \$10 gift card for beginning the study, \$10 after completing COPE2Thrive, and \$15 after completing the questions for the last time. In order to pay you, we will need your email address, which will be used on the gift card service called Tango.

Do my parents need to know about this study?

Yes, your parents/guardian will have to sign a permission form (like this one) to allow you to participate, and know what the study is generally about, but they do NOT need to know the details of why you are invited to join; they will also NOT have access to the answers you are giving in your surveys should you choose to participate. *Your parent/guardian will also be*

asked to answer questions about how they think you are doing. Your parent/guardian will not have access to your specific responses to anything we ask you. However, if we learn that you are a danger to yourself or others, the law requires us to let your parents/guardians know and get you the help you need.

Who else will know that I am in the study?

No one except your parents/guardians, the research team, and anyone with access to your electronic health record will know that you have taken part in this study, but your answers will not be shared with your parents/guardians, and your parents/guardian's answers won't be shared with you. A note may be added to your medical record documenting your participation. The only exception to this is if we learn that you are a danger to yourself or others or if you tell us, you are being abused or neglected. Then, as required by law, we may be required to let others know about your involvement in this study in order to help you and keep you safe. Our research team will make every effort to make sure you are able to be in a safe space when responding to the questions.

What are the costs to take part in this study?

There are no costs to being in the study, but it will take up some of your time. The COPE2Thrive program will take approximately four hours to complete, some of which may happen during the school day but will not get in the way of your classes.

What if I am injured in this study?

The study is only about learning how you feel, and so it is very unlikely that you will be injured. It is possible that you might feel upset about questions that ask about feelings or behaviors.

Who do I call if I have questions or problems?

If you have any study-related questions or concerns as a result of being in this study, please contact the research assistant

Research Assistant

Telephone: 617-806-8780

Email: ALACRITY-R34-1@challiance.org

In case of emergency, please call 911 or go to the nearest emergency room, or you may contact the National Suicide Prevention Lifeline 1-800-273-8255.

What are my rights when I am in the study?

You do not have to be in the study if you do not want to. It is totally voluntary. Your participation in this research study requires select members of the research team to access information in your CHA electronic health record. This information includes past or current care at CHA, and other relevant information related to your care. You can stop being in this study at any time for any reason. There are some questions we would want to ask you before you stop being in this study. If you do not want to take part or leave the study, we will not be angry with you.

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Any information collected from you before the date you leave the study will be used in the research study.

If you have questions about your rights, you may call the IRB Chair at (617) 806-8702. You may also call the Cambridge Health Alliance Patient Relations Manager at 617-665-1398.

Once you have made your decision, please check one of the boxes below and sign your name. You will be given a copy of this assent form to keep once it has been signed.

Signature of Adolescent

Printed Name of Adolescent

Signature of Person Getting Assent

Printed Name of Person Getting Assent

Date

