CHA Cambridge Health Alliance	**INFORMED CONSENT AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH**

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.

Study Title: Stress and Coping Among High School Students (ALACRITY eSToRY R34 #1)

Your name (Participant):	**Today's Date:**

Not including this study, are you taking part in any research now? ☐ **Yes** ☐ **No**

Name of Principal Investigator: Margaret Weiss, MD, PhD

Name of Co-Investigator(s): Eleanor Richards, PhD

Consent form version date or number: 07/25/2023 v9

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**

Key Information

- **Consent:** Your agreement to take part in this research project is voluntary. You do not have to agree to participate and you can stop them at any time. You will not be punished or lose any benefits that you are owed.
- **Purpose:** This study is being done to try to find out more about what emotional challenges teens are coping with, and to know how to better help them.

- **Risks:** The main risk of this study is the distress you may feel from talking about difficult experiences you have had. You can stop at anytime, and you do not have to answer any questions you do not want to answer.
- **Benefits:** You may find that by joining our study, you become more aware of any stress or other difficulties you are having, and learn coping skills to better handle this stress.
- **Alternatives:** Taking part in the study is optional. You may leave the study at any time.

Introduction

We as researchers hope to help you and other teens like you. Research is a special way to learn about something new. In this study, you will be able to take part in an online research intervention program called COPE2Thrive. COPE2Thrive is an intervention that helps teens learn how to deal with stress. We want to learn how you feel before and after the program.

You are invited to take part in this research study. Taking part in this study is optional. You have the choice to take part or not. If you take part in the study, you may leave the study at any time. There are no consequences if you do not want to take part in our study. This is the second portion of the study that you have already completed the first screening portion of. If you don't want to take part, it does not change any part of the standard health care you may receive at Cambridge Health Alliance. There are no consequences if you do not want to take part in our study.

If you decide to take part in this study, you will be asked to sign this form. A copy of the signed form will be shared with you. Please keep your copy. It has information, including important names and telephone numbers.

Purpose of the study

This study is being done to try to find out more about what emotional challenges teenagers are facing now, and whether an online program aimed at improving emotional wellbeing, COPE2Thrive, is helpful. Approximately 108 participants will be in this study at Cambridge Health Alliance.

Reasons why you have been invited to be in this study

You have been invited to be part of this research study because you are a high school student in one of Cambridge Health Alliance's service areas (Cambridge, Everett, Lynn, Malden, Revere, Somerville or Winthrop).

Period of participation (how long you will be in this study)

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

Procedures (what will happen during this study)

If you choose to participate in this research study, you will be offered an online program, called COPE2Thrive, to build coping skills. Before the program starts, you will answer questions about how you are doing. Your

parent/guardian will also answer questions about how they think you are doing. You will not have access to your parent/guardian's answers.

The online program (COPE2Thrive) has seven parts that teach about different ways of improving coping and well-being. 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. All participants will have the opportunity to participate in the COPE2Thrive intervention. Individuals will participate in COPE2Thrive at different times. You may have to wait for a brief period of time until it is your turn to do COPE2Thrive. You will have two months to complete the program.

The information you give us is confidential. The information we are collecting is for research purposes and cannot be used to provide information on diagnosis or other specific clinical questions. However, if we learn that you are a danger to yourself or others, the law requires us to let appropriate personnel know and get you the help you need, which in an emergency situation might include contacting others, including your parent or guardian. If you tell us that you are being abused or neglected, we are required to inform the Department of Children and Families.

Collection of identifiable private information or identifiable biospecimens

In this study, we will give your information a code, instead of using your name. We save the codes separately from your information. In this way, no one can identify your information without the code. When the research project is complete, we will delete the key to the code so no one, not even our research team, can identify you. This is called "de-identified" information. This protects your privacy. We may share our data with other researchers, including NIMH (The National Institute of Mental Health), but this data will not include anything specific that can be connected to you. To begin the online coping intervention, you will be asked to create a COPE2Thrive account which will include entering your name, email, and creating a password for the site. Our research team will not have access to this information or your account.

After identifiers are removed from identifiable private information, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Possible Risks, Discomforts, Side Effects, and Inconveniences

If you decide to participate, you will 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.

Alternatives to Participation

You do not have to be in the study if you do not want to. It is completely voluntary. You can stop being in this study at any time for any reason. Please contact us if you decide to stop participating.

Benefits (good that may come from being in this research)

You may find that by joining our study, you become more aware of any stress or other difficulties you are having, and learn coping skills to better handle these stresses.

Costs

If you take part in this study, there will be no financial costs to you. The only cost will be your time.

Payment

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. The COPE2Thrive Intervention will be provided at no cost to you.

Study-Related Injury

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. 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.

Voluntary Participation

Taking part in this study is **voluntary**. If you do not wish to take part, you will not be punished or lose benefits that you have the right to receive. If you choose to participate and then you decide to stop, call the research assistant(617-806-8756). You may withdraw your consent at any time, and you may leave the study at any time.

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

The research team may decide that you can no longer be in the study. This could be for several reasons, including:

1. You have had a bad reaction to the study.
2. You did not follow all the study rules.

Privacy / Confidentiality

There are laws (state and national) that protect health information to keep it private. We follow those laws. Your identity, medical records, and study data will be kept confidential, except as required by law.

We will protect all of your health information, including your Protected Health Information or "PHI." Your PHI is your individually identifiable health information.

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. Do not take part in this study if you do not want the research team to access your CHA health information.

We will follow these guides:

- The research team will view your health information only during the life of this study.
- We will not include any information that could identify you in any publication.
- At the end of the study, we will remove all identifiable information (name, address, telephone number, *etc.*) from the study database.

We will make every effort to keep your information private, but we cannot guarantee it. The Cambridge Health Alliance Institutional Review Board (IRB) is responsible for protecting the safety and welfare of people who take part in research studies at our hospital. IRB staff may ask to look at any research records to make sure the study team is following the laws and rules to protect you. Certain government agencies, including the Office for Human Research Protections and the U.S. Food and Drug Administration (regulates drug and device studies), may also look at records that identify you.

Sometimes, we are required to share your study records with others, too, including:

- Other researchers conducting this study,
- The study sponsor and any companies that the sponsor uses to oversee, manage, or conduct the study
- Accrediting agencies
- Clinical staff not involved in the study, but involved in your regular treatment,

If any of these groups ask to look at your information, then we cannot prevent it from being shared. Once information is shared, we cannot guarantee any further confidentiality and privacy.

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.

A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by US 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.

Period of Authorization

Your Authorization remains in effect until the end of the study and any applicable record retention period. The Principal Investigator will securely store study information for 7-years after the study has ended as per IRB protocol. If you change your mind and want to withdraw your authorization please tell a member of the study team or write to the HIPAA Privacy Officer for Research, Cambridge Health Alliance, 1493 Cambridge Street, Cambridge, MA 02139. If you withdraw your authorization, you may no longer be allowed to participate in the study described in this form.

Members of the investigator's study team at Cambridge Health Alliance may conduct additional studies in the future that are unrelated to this one. Would you like to be contacted by the CHA Research Team about other research projects in the future?

☐ Yes ☐ No Initials _____

Getting Help (Contacts)

If you have questions about this study please ask a member of the study team. Some questions people have:

- What are the risks and benefits of being in this study?
- What other choices are available?
- What are my rights as a research participant?
- What should I do if I feel pressured to take part in this study?
- How is my health information used in this study?
- How will my health information be protected?

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

Additionally, if you have questions about your rights as a study participant, please contact either the IRB office or the Patient Relations Department. The offices are open Monday to Friday (not holidays) from 8:30am until 5:00pm:

IRB Chair:
Telephone: 617-806-8702

Patient Relations Manager
Telephone: 617-665-1398

Confirmation from Person Obtaining and Documenting Consent

I have read this form or it has been read to me. I understand my part in this study and have had my questions answered to my satisfaction. I agree to take part in this research study, as indicated below.

Check one box only:

☐ Yes, I agree to take part in the first part of this research study.

☐ No, I do not want to take part in this research study.

_____ _____

Participant's Signature Date

I have informed the study participant, _____ of:
Participants Printed Name

- The procedures, purpose, and risks related to participation in the above-described study;
- How his/her/their information may be used, shared, and reported, and;
- His/her/their privacy rights.

The study participants have been provided with a signed copy of this form.

_____ _____

Signature of Researcher Obtaining Consent Date

_____

Printed Name of Researcher Obtaining Consent

_____ Interpreter Role ❒ CHA employee

Printed Interpreter Printed Name (if used) ❒ Other_____