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: 08/10/22 v2

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

- We are holding interviews to better understand your experience and your child's experience with the onlineCOPE2Thrive program andthe COVID-19 pandemic.Your agreement to participate and allow your child to participate is voluntary.
- Interviews will be done through a phone call and will take approximately60 minutes for each person.
- The only risk of the study is that some of the questions might make you uncomfortable.
- Benefits: Your answers will provide useful information regarding lived experience through COVID-19 and how to better help youth in the future.

Introduction

We want to talk to you and your child about your experience taking part in a research study. We hope to learn about the emotional well-being of youth and their experience with the COPE2Thrive program.

Taking part in this study is voluntary.If you take part in the study, you may leave the study at any time for any reason. 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.

If you decide to take part in this study, you will be asked to sign this form. We will give you a copy of the signed form. Please keep your copy for your records. It has information, including important names and telephone numbers, for future reference.

Purpose of the Study

The purpose of this study is to learn more about your child's experience with COPE2Thrive and to learn more about your experience through the COVID-19 pandemic. You will be asked for feedback about the research study and the COPE2Thrive program your child participated in. Questions may include whether it met your expectations, what your interactions with study staff were, and how the program impacted your child.

Reasons why you have been invited to be in this study

The reason why you have been invited to be part of this interview is because your child has participated in the online COPE2Thrive resilience-building program through a research study based at CHA in Everett, Somerville, Cambridge, Chelsea, Malden, Winthrop, or Revere.

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

If you choose to take part in this research study, you will be included in an interview that will last for about one hour.

Procedures (what will happen during this study)

If you decide to take part in this research study, the following procedures will take place:

- We will ask you if you would like to participate in the study and document this in our records. We will be collecting written consent from you via this form, and you will have a copy of this form sent to your email address for your records. If you consent, we will schedule a time to call you back for the interview.
- We will call you at the scheduled time for the interview. The interview will be recorded and we will remind you of this at the beginning of the call. The interview will take approximately 60 minutes, and we will ask questions about you and your child's experience with the research project and COPE2Thrive program. We will also ask questions related to your experience during the COVID-19 pandemic.
- You can decide to stop at any time. Tell the study researcher right away if you wish to stop answering questions during the interview.

Collection of identifiable private information or identifiable biospecimens

- In this study, we will give your child's information a code instead of using their name. We save the codes separately from their answers. In this way, no one can identify their 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 your child's answers. This protects your child's privacy. We may share our data with other researchers, including NIMH (The National Institute of Mental Health), but this data does not include anything specific that can be connected to your child.
- After identifiers are removed, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

Possible Risks, Discomforts, Side Effects, and Inconveniences

If you decide to participate, some of the questions asked during the interview may make you feel uncomfortable, but you may choose to not answer any questions you do not wish to answer or to stop the interview at any time.

We will not be asking questions about the following topics, but if you share information about child or elder abuse we are required to report them to the appropriate authorities.

Some of the questions that you will be asked are of a personal nature. They may cause you to be embarrassed or stressed. You can choose not to answer a question or stop the interview at any time if you find these questions uncomfortable. We are happy to answer any questions you may have about these risks. Please talk with a study team member if you feel uncomfortable or have any study-related questions or concerns.

Your part in this interview consists of allowing the research team to use data from your child's medical record. This study does not require you to have any additional procedures or treatments. Therefore, being in this study does not involve any risks that you would not face during your routine treatment and care.

Alternatives to Participation

If you choose not to participate in this study, you will not be penalized in any way. Your current and future health care or employment will not be affected.

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

The information that you provide during the interview may help health professionals learn more about the barriers you and others may have faced due to COVID-19 and the types of resources that youth may need right now.

Costs

There are no costs to participate in this study.

Payment

For participating in the study, you will be given a $50 gift card. The gift card will be emailed to you through an online gift card service called Tango.

Study-Related Injury

This interview is only going to have you answer questions on your feelings on the COPE2Thrive modules and the COVID-19 pandemic. It is unlikely you will be injured in this study, but you might feel uncomfortable answering these questions.

Voluntary Participation

Taking part in this study is voluntary. If you do not take part, you will not be punished or lose benefits that you have the right to receive. If you receive medical care at Cambridge Health Alliance, the quality of your medical care will be the same at Cambridge Health Alliance whether you take part in the study, refuse to take part, or decide to leave the study. With the exception of voicing threats to harm yourself or others, abuse or neglect, anything you say during the interview is strictly confidential, and your providers at CHA (if you are a CHA patient) will not know anything you share with the interview. In the event that you do share a threat of harm to yourself or someone else during the interview, we are required to notify the appropriate safety personnel (as listed above: "Possible Risks, Discomforts, Side Effects, and Inconveniences.")

If you choose to take part in this study and then decide to stop, tell a member of the research team.

Privacy / Confidentiality

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

We will protect all of yours and your child's health information, including your Protected Health Health Information or "PHI". Yours and your child's PHI individually identifiable health information.
If you take part in this study, you agree to let the research team access your child's medical information. Do not take part in this study if you do not want the research team to access your child's health information.

We will follow these guidelines:

- The research team will view your child's health information only during the life of this study.
- We will not include any information that could identify you or your child in any publication.
- At the end of the study, we will remove all of your 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, and

- Accrediting agencies

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

Period of Authorization

Your authorization expires when this study is terminated. If you change your mind and want to withdraw your authorization please tell a member of the study team. If you withdraw your authorization, you may no longer be allowed to participate in the study described in this form.

Getting Help (Contacts)

Please feel free to ask us anything you would like before signing this consent.If you have any questions about this study please ask a member of the study team. Some questions people have are:

- 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 about your child as a result of being in this study please contact the Principal Investigators:

Maragaret Weiss
Telephone: 857 317 0559

Or

Eleanor Richards
Telephone: 617-575-5193

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, the study participant, 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.

_____ _____

Participant's Signature Date

I have informed the study participant, _____ of:
Participant's Printed Name

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

The study participant has been provided with a signed copy of this form.

_____ _____

Signature of Researcher Obtaining Consent Date

_____

Printed Name of Researcher Obtaining Consent

_____ _____

Signature of Participant's Legally Authorized Representative Date

_____ _____

Printed name of Participant's Legally Authorized Representative Date

_____ Interpreter Role ❒ CHA employee

Printed Interpreter Printed Name (if used) ❒ Other_____