



**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 child's name (Participant):

Today's Date:

Your name (Guardian Participant):

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: 07/25/23 v11

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 allow your child to take part in this research project is voluntary. You do not have to agree to your child's participation 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 youth are coping with, and to know how better to help them.
- **Risks:** The main risk of this study is the distress your child may feel from talking about difficult experiences they have had. Your child will be reminded they can stop anytime, and that they do not have to answer any questions they do not want to answer.
- **Benefits:** Your child may find it helpful to learn about themselves through the screening. They may also appreciate that other youth like them may benefit from what we learn from your child in this study.
- **Alternatives:** Taking part in the study is optional. You or your child may leave the study at any time.

Introduction

We want to talk to you and your child about a research study. We as researchers hope to help your child and others like them, and research is a special way to learn about something new. We hope to learn more about the emotional well being of youth. After the assessment, your child will be invited to participate in a study of an online program to improve emotional well being, or if needed and they are interested we will provide your child with information about how to obtain more support and/or mental health treatment..

Taking part in this study is optional. You have the choice to let your child take part or not. If your child takes part in the study, your child may leave the study at any time. There are no consequences if you or your child do not want to take part in our study. 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 let your child take part in this study, you will be provided a copy of this form. 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 to know how to better help them. Approximately 400 participants will be in this study at Cambridge Health Alliance.

Reasons why your child has been invited to be in this study

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

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

This study is only to find out how your child is doing right now. The assessment will take about half an hour. If your child wants to participate in our study of the online program aimed at improving emotional wellness, we may refer them to that program.

Procedures (what will happen during this study)

If you choose to let your child participate in this research study, your child will complete an online questionnaire to tell us how they are doing. One of our research team members will help them to complete this assessment. The information we are collecting is for research purposes and cannot be used to provide information on diagnosis or other specific clinical questions.

The information they give us is confidential. However, if we learn that your child is a danger to themselves or others, we have to by law let you know and get them the help they need. If they tell us that they are being abused or neglected, we are required to inform the Department of Children and Families.

After they complete this online questionnaire, they will be asked if they are interested in another part of our study to look at whether an online program aimed at improving their emotional wellbeing is helpful. If we learn that they are having significant emotional or behavior problems, we will ask their permission to inform you so that we can provide them with information about how to obtain more support and/or mental health treatment. If your child does not give us permission to inform you of these emotional or behavioral problems, we will not notify you, and we will not provide details if you reach out to the study coordinators.

Collection of identifiable private information

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 to the online questionnaire. 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 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 the subject or the legally authorized representative.

Once your child is finished with the study, our research team will continue to review the information they gave us to help us learn new things about how youth are able to learn about their emotions and access mental health care if needed. By providing verbal authorization of consent, you are also giving our research team permission to access your child's electronic health record (if through CHA) for other components of this study.

Possible Risks, Discomforts, Side Effects, and Inconveniences

Your child will be asked to answer personal questions about their feelings and behaviors. These might make them feel uncomfortable, and may make them aware of any emotional difficulties they have been struggling with. The online questionnaires are designed to be secure and protect your child's confidential information, but any online information may be susceptible to privacy breaches. There is a remote risk of loss of data confidentiality. The study will require some time to complete.

Alternatives to Participation

Your child does not have to be in the study if they do not want to. It is totally voluntary. They can stop being in this study at any time for any reason.

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

Your child may find that by joining our study, they become more aware of challenges they are having, which might help them begin to address these challenges.

Costs

If your child takes part in this study, there will be no financial costs to you or them. The only cost will be their time.

Payment

Your child will be paid with a gift card for \$10.00 after taking the online screening. In order to pay them, we will need their email address, which will be used on the gift card service called Tango.

Study-Related Injury

This study is only about learning how your child feels, and so it is very unlikely that they will be injured. It is possible that they might feel upset about questions that ask about feelings or behaviors. If your child is identified by the research team as requiring emergency care, all needed emergency care is available to them, just as it is to the general public. Any needed medical care is available to them 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 child's treatment if treatment is recommended by the research team.

Voluntary Participation

Taking part in this study is **voluntary**. If you do not wish for your child to take part, they will not be punished or lose any benefits that they have the right to receive. You may withdraw your consent on behalf of your child at any time, and your child may leave the study at any time.

Any information collected from your child before the date they leave the study will be used in the research study.

The research team may decide that your child can no longer be in the study. This could be for several reasons, including that they are unable to understand the questions, or cannot follow the study instructions.

Privacy / Confidentiality

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

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

Your child's participation in this research study requires select members of the research team to access information in their electronic health record. This information includes past or current care at CHA, and other relevant information related to their care.

We will follow these guides:

- 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 your child in any publication.
- At the end of the study, we will remove all identifiable information (name, address, telephone number, *etc.*) of your child from our records.

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 your child. 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 your child.

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 child's 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.ClinicalTrials.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, your child 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 ____

Getting Help (Contacts)

Please feel free to ask us anything you would like prior to authorizing your consent.

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 child's rights as a research participant?
- What should I do if I feel pressured to let my child take part in this study?
- How is my child's health information used in this study?
- How will my child's 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 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 child's 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

Check one box only:

☐ Verbal authorization provided

COMPONENT 1 INFORMED CONSENT (PARENT/GUARDIAN)

☐ Verbal authorization not provided

I have informed the study participant's parent/guardian, _____ of:
Parent/Guardian Printed Name

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

The study participant's parent/guardian has been provided with a 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 _____

