

Study Title: ABC Mental Health: A Behavioral Study of K-12 Teachers and School Staff

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Consent to Participate in a Research Study

ADULT

ABC Mental Health: A behavioral study of K-12 teachers and school staff

CONCISE SUMMARY

This study looks at school employees' mental health, well-being, and effectiveness (your ability to teach effectively) before and after completing a professional development workshop. Your school is offering the Cultivating Awareness and Resilience in Education (CARE) professional development workshop to all teachers, staff, and administrators. CARE will be presented in one to four in-person training sessions over one to four months.

People who participate in CARE are asked to answer questions about their demographic information, mental health, well-being, and effectiveness before the workshop and two times after completing the workshop. This consent form provides the necessary information for people interested in answering these questions to make an informed decision. This consent form is not for the professional development workshop. Taking part in the workshop and questionnaires is optional.

This study is being conducted because teachers, school staff, and children's mental health has declined since the beginning of the COVID-19 pandemic. We hope to use information collected in this study to tell schools, local public health officials, and state leaders how best to support teachers' mental health and well-being.

There are minimal risks associated with this study. The greatest risk of this study is loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this study because you are 18 years or older, speak the English language fluently, and are employed by a K-12 school.

This study and the professional development workshop (CARE) is funded by the National Institute of Child Health & Human Development (NICHD). All activities are overseen by the Duke Clinical Research Institute (DCRI) Coordinating Center, which includes the ABC Science Collaborative. The principal investigator at DCRI, who is responsible for the study, is Dr. Emily M. D'Agostino.

WHY IS THIS STUDY BEING DONE?

This study is being conducted because teachers, school staff, and children's mental health has declined since the beginning of the COVID-19 pandemic. Your school offers the professional development workshop Cultivating Awareness and Resilience in Education (CARE) to all teachers, staff, and administrators. Teachers and staff attend the workshop together, but administrators attend a separate



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workshop to address their needs. CARE will be presented in one to four in-person training sessions over one to four months.

The professional development workshop may help school employees apply tools to reduce stress and improve well-being and effectiveness. It could also positively impact children's mental health. As part of the "ABC Mental Health: A behavioral study of K-12 teachers and school staff" study, people who participate in CARE are asked to answer questions about demographic information, mental health, well-being, and effectiveness before and twice after completing the one to four-day workshop. We hope to use information collected in this study to tell schools, local public health officials, and state leaders how best to support teachers' mental health and well-being.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

We expect that up to 1,000 participants like you will take part in this study.

WHAT IS INVOLVED IN THIS STUDY?

We are interested in understanding the impact of the CARE professional development workshop on your mental health, well-being, and effectiveness.

If you choose to take part in this study:

- You will be asked to sign and date this electronic consent form.
- You will have the opportunity to create a profile on the online Duke REDCap system and answer a series of questions including the following:
 - **Demographic information** (information about who you are)
 - **Health information**, such as mental health and well-being
 - **Work effectiveness**, such as student instruction and behavior management
- The questions will take approximately 45 minutes to complete.
- Even though these questionnaires are optional, your responses are very important, and will help researchers examine the mental health, well-being, and effectiveness of teachers, staff and administrators before and after completing CARE.
- You will be asked to complete the questionnaires three times during your participation in this study:
 1. Up to one month prior to the workshop,
 2. One week after completion of the workshop, and
 3. Two months after completion of the workshop.
- You will be asked to sign this consent form prior to completing each questionnaire.



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- You will have the option to choose if you would like to share certain identifiable information and with whom.

Taking part in this study is voluntary. You can choose to stop at any time without any penalty. We will use the data you provide until you choose to stop participating.

HOW LONG WILL I BE IN THIS STUDY?

The study will continue for up to 2 years. Your participation in the study will last up to 1 year. Reasons your participation could end (with or without your permission) may be:

- The study ends.
- You do not agree with consent updates.
- The principal investigator or team who oversees research recommends you no longer take part.
- The sponsor ends the study.

There may be other reasons not listed here. If your participation ends without your permission, you will be notified of the reason.

If you agree to take part, a copy of this signed consent form will be available to you through the online system.

WHAT ARE THE RISKS OF THE STUDY?

There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality – meaning that your data could be tied back to you. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. You may refuse to answer any of the questions, and you may take a break at any time during the questionnaires. You may stop your participation in this study at any time.

Risks specific to online data collection:

Information collected by an online system are subject to their terms of use, which you should read carefully.

If you are accessing the online system and answering the questions on your phone, it may impact the operations of your device (e.g., battery drainage). If you do not have an unlimited data/text plan, you may incur additional charges.

We are not asking you to make any health decisions based on the use of this online system. You should discuss health decisions directly with your healthcare provider.



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As with all technology, we ask you to wait until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You may or may not benefit by participating in this study. You may experience an improvement in your mental health, well-being, and effectiveness at work. Your participation may contribute to research on school employee resiliency and help determine how schools can best support teachers', staff's and administrators' mental health, well-being and effectiveness.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Your privacy is very important to us. We will take great care to protect your privacy. However, there is always a chance that, even with our best efforts, your identity and/or information collected during this study may be accidentally released or seen by unauthorized persons. Here are a few steps we will take:

- Data will be stored on protected, secure computer systems. We will limit and keep track of who can see these data.
- Anyone who can see these data will have to use a password.
- We will take steps to protect your information from others that should not be able to see it.
- When your data are shared with other researchers, they will not have information that can identify you.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

- 1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
- 2) you have consented to the disclosure, including for your medical treatment; or
- 3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your



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family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

As part of the study, Dr. Emily M. D'Agostino and her study team will report the results of your study-related questionnaires to NICHD and collaborators of the ABC Science Collaborative. The results of your study-related questionnaires, which will not have information that can identify you, will be shared with your school district and possibly with other participating school districts. We will keep your data secure (which means with extra protection). This information may be further disclosed by the sponsor of this study, NICHD. If disclosed by the sponsor, the information is no longer covered by the federal privacy regulations. In addition, your records may be reviewed in order to meet federal or state regulations.

Reviewers may include representatives and affiliates of NICHD, the Duke University Health System Institutional Review Board, and others as appropriate.

The study results will be retained in your research record for five years after the study is completed, as per Duke policy.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

HOW WILL MY DATA BE USED?

An electronic database called REDCap (kept at the DCRI) will hold all information you choose to share during your participation in this study. This includes information that can identify you (called identifiable information). An example of identifiable information is your name, physical address, and email address.

- Your name, physical address, and email address will be requested for the purpose of paying you for completing each questionnaire and will be securely stored.
- You may choose to not share your physical address, and email address and still complete the questionnaires.
- If you choose not to share your physical address, and email address, you cannot be paid for completing each of the questionnaires.
- Your name, physical address, and email address must be collected for the purpose of payment documentation because payment for participation in research (such as a gift card) is considered



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taxable income to the research participant and Duke University is required in many cases to report this information to the Internal Revenue Service (IRS).

- If you choose to receive payment, your name and email address will be provided to Amazon.com, Inc. so they can send you the electronic gift card.
- Before completing each of the three questionnaires, you will be provided with a separate electronic form to identify if you would like to share your physical address, and email address for the purpose of payment. If you choose to share this information, you will be requested to provide your email address and complete an electronic form in REDCap that:
 - Explains why your personal identifiers are required.
 - Collects your name, and physical address.
 - Asks you sign the completed form.

The REDCap database will also hold information that does not identify you (will be assigned a study code). It will hold all the non-identifiable (cannot link the data back to you) information you agree to give. Examples are your responses to the questionnaires.

- We plan to transfer and keep these non-identifiable data in a secure database at the NIH. Other researchers may use these data for studies, other than the ones stated in this consent form.

WHO WILL ACCESS MY DATA AND IN WHAT FORM?

This study is using a secure online platform, known as the Duke REDCap system. Your data will be sent directly from the online system to DCRI.

By agreeing to take part, the information you share may be used by other researchers in the future. If your data is used in this way, identifying information (name, street address, phone number, email address) will be removed.

The Institutional Review Board (IRB) or other regulatory agencies may use your data to monitor research conduct and ethics, or in a way that is required by law.

By consenting to take part, you agree to allow access to your data for these reasons.

WHAT ARE THE COSTS TO YOU?

There are no costs to you to join this study. If you access the study using a mobile device, you will be responsible for any data usage or other charges from your wireless service provider.



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WHAT ABOUT COMPENSATION?

You have the option to receive a \$25.00 electronic Amazon gift card for each questionnaire you complete. If you complete all three questionnaires, you will receive a total of \$75.00. We will ask you to share personal identifiers, including name, physical address, and email address, for the purpose of payment. If you choose to share this information and receive payment, your name and email address will be provided to Amazon.com, Inc. so they can send you the electronic gift card to your email address approximately one week after you complete each of the questionnaires. You may choose to not share your physical address, and email address and still complete the questionnaires. If you choose not to share these personal identifiers, you cannot receive payment. You will be asked in a separate electronic form in REDCap whether you would like to share these personal identifiers for the purpose of payment.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to participate in or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Emily M. D'Agostino in writing and let her know that you are withdrawing from the study. Her mailing address is Department of Orthopedic Surgery, Duke University School of Medicine, 311 Trent Drive, Durham, NC 27710.

This consent form is for participation in answering the questionnaire, not for the professional development workshop. Taking part in the workshop and questionnaires is optional.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

WHOM DO I CONTACT IF I HAVE QUESTIONS OR PROBLEMS?

If you have problems, concerns, questions or suggestions about the research, you may contact the DCRI ABC research team at SchoolSETStudy@duke.edu.



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For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

STATEMENTS OF CONSENT

Please confirm the following statements and check the box to provide your consent. A copy of the signed consent form will be made available to you. Providing consent confirms that you:

- Are 18 years of age or older
- Are staff, a teacher or administrator of a K-12 school
- Speak the English language fluently
- Have read and understood the information provided
- Have had enough time to think about the information and get answers to any questions
- Understand that you do not have to take part, and confirm that you are giving your consent freely

The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have any questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form.

Signature of Subject

Date of Signature

Printed Name of Subject

You can review this information as many times as you'd like. You can reach out to us with questions at SchoolSETStudy@duke.edu.