

Official Title: The I-ACTED Study: Testing the Causal Effects of a Civic Engagement Intervention on Health and Wellbeing Among Youth

NCT04514133

IRB Approval Date: 08/04/2025

THE I-ACTED STUDY

Parent/Guardian information consent form
Parissa J. Ballard, PhD, Principal Investigator

SUMMARY

Your child is invited to participate in a research study. The purpose of this research is to understand how teacher's participation in a professional development curriculum is associated with student's civic outcomes, and health and wellbeing. Your child is invited to be in this study because they are enrolled in a school where this study is taking place. Your child's participation in this research will involve them completing surveys in class and online surveys out of class.

Participation in this study will involve your child completing surveys about their health, wellbeing, and participation in their community.

Your child's participation in this study is voluntary. Your child does not have to participate in this study if your child does not want to. Your child will not lose any benefits that they would normally have if they choose not to participate.

The remainder of this form contains a more complete description of this study.. Please read this description carefully. Your child can ask any questions if your child needs help deciding whether to join the study. The person in charge of this study is Dr. Parissa J. Ballard, (the Principal Investigator). If your child has questions, suggestions, or concerns regarding this study or your child wants to withdraw from the study, he/she may contact Dr. Parissa J. Ballard at ([REDACTED] or [REDACTED]), or the project manager, Grisel Trejo, at [REDACTED] or [REDACTED]. If your child has any questions, suggestions or concerns about his/her rights as a volunteer in this research, contact the Institutional Review Board at [REDACTED].

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 2500 students from approximately 50 schools will participate in this study.

WHAT IS INVOLVED IN THE STUDY?

If your child takes part in this study, your child will complete surveys during class time about their health, wellbeing, participation in their community, and knowledge about civics. They will also be invited to participate in online surveys in the future.

HOW LONG WILL MY CHILD BE IN THE STUDY?

Your child will be in the study for about 1 year. we may try to follow-up and invite them to complete additional online surveys after 1 year. Your child can stop participating at any time.

WHAT ARE THE RISKS OF THE STUDY?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations

or tests. Your child does not have to answer any of the questions they don't want to answer. In addition, there is a slight risk of a breach of confidentiality. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your child's information safe. As part of this study, your child will be asked questions about depression. If we learn that your child or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Your child is not expected to receive any direct benefit from taking part in this research study. He/she may enjoy sharing their opinions on topics covered in the survey. We hope the information learned from this study will benefit other people in the future.

WILL MY CHILD'S RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals; these findings will be presented in aggregated form and we will not identify your child alongside the information they provide for this study. Your child's identity and/or your child's personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of your child or others. There is always some risk that even de-identified information might be re-identified.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by Robert Wood Johnson Foundation, which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you 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. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as child abuse and neglect, or harm to self or others.

WILL MY CHILD BE PAID FOR PARTICIPATING?

Your child will not be paid for participating in the study. However, for the first two surveys, students who complete the survey will be entered into a raffle for a chance to win a \$25 gift card. Two students will be chosen for each survey wave. Every student will also receive a \$5 gift card for completing the third survey.

WHO IS SPONSORING THE STUDY?

This study is being sponsored by the Robert Wood Johnson Foundation. The sponsor is providing money or other support to the researchers to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ABOUT MY CHILD'S HEALTH INFORMATION?

In this research study, any new information we collect from your child about your child's health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: their self-assessment of physical and mental health and health behaviors.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from your child during this study may be placed in your child's medical record, and may be used to help treat your child, arrange payment for your child's care, or assist with Medical Center operations.

We will make every effort to keep your child's Protected Health Information private. We will store records of your child's Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your child's personal health information and information that identifies your child ("your child's health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

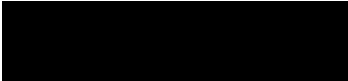
Some of the people, agencies and businesses that may receive and use your child's health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your child's health information. If disclosed by them, your child's health information may no longer be covered by federal or state privacy regulations. Your child's health information may be disclosed if required by law. Your child's health information may be used to create information that does not directly identify your child. This information may be used by other researchers. Your child will not be directly identified in any publication or presentation that may result from this study unless there

are photographs or recorded media which are identifiable.

Any Protected Health Information collected from your child in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your child's medical record will either be destroyed or it will be de-identified.

You can tell Dr. Parissa J. Ballard that you want to take away your child's permission to use and share your child's Protected Health Information at any time by sending a letter to this address:

Dr. Parissa J. Ballard


However, if you take away permission to use your child's Protected Health Information your child will not be able to be in the study any longer. We will stop collecting any more information about your child, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your child's Protected Health Information for this study.




If your child chooses to participate in this study, your child's medical record at Wake Forest University Baptist Medical Center will indicate that your child is enrolled in a clinical trial. Information about the research and any medications or devices your child are being given as a participant may also be included in your child's medical record. This part of the medical record will only be available to people who have authorized access to your child's medical record. If your child is not a patient at this Medical Center, a medical record will be created for your child anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify your child. At most, the website will include a summary of the results. You can search this Web site at any time.

WHAT ARE MY CHILD'S RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. Your child may choose not to take part or your child may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which your child are entitled. If your child decides to stop participating in the study, we encourage you to talk to the investigators or study staff first. The investigators also have the right to stop your child's participation in the study at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study, contact the study investigator, Parissa J. Ballard at  or the project manager, Grisel Trejo, at  or .

The Institutional Review Board (IRB) is a group of people who review the research to protect

your child's rights. If you have a question about your child's rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, You should contact the Chairman of the IRB at [REDACTED].

What does my signature on this consent form mean?

Your signature on this form means that:

- You understand the information given to you in this form.
- You have been given the opportunity to ask the researcher questions and state any concerns.
- The researcher has responded to your questions and concerns, if applicable.
- You believe you understand the research study and the potential benefits and risks that are involved for your child.
- You understand that even if you give your permission, you child may choose not to take part in the study.

Statement of Consent

Summary: Participation in this study will involve your child completing surveys about their health, wellbeing, and participation in their community.

- ☐ I give my permission for my child to take part in this study.
- ☐ No, I do not give permission for my child to participate.

Signature of Parent/Guardian _____ Date: _____ Time: _____ am pm

Printed Name of Parent/Guardian: _____

Printed Name of Minor: _____