

**Study Title:** Development and Testing of ADEPT: A Parent Decision Support for Childhood Vaccinations

**NCT#:** NCT04496453

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# ADEPT Study

This is a copy of the content provided in the phone consent survey.

IRB #: Pro00101904

Principal Investigator: Dr. Lavanya Vasudevan

This study is being led by Dr. Lavanya Vasudevan, Ph.D., from the Duke Department of Community and Family Medicine. The goal of the study is to put together a guide about childhood vaccines for parents. We hope this guide will help new or expecting parents as they make choices about vaccines for their child. Since you are the parent/primary caregiver of a young child and/or an expecting parent, we would like to talk to you about the guide.

You can choose whether or not to take part in this study. If you choose to be part of the study, someone from the study team will share the guide on childhood vaccines with you by email or another way that works for you. You will be given time to review the guide on your own. We think it will take about 15-30 minutes for you to review the guide. After you have looked at the guide, you will be asked to join us for a discussion about the guide. During this discussion, someone from the study team will ask you for your thoughts and feedback on the guide - what you liked about it and what you did not like. The discussion will be conducted in English over Zoom or telephone and will take no more than 1.5 hours. Depending on how many people participate in the study, we may invite you to the discussion by yourself or with a group of up to 3 other participants.

You will also be asked to complete two brief surveys, one immediately after you complete this consent and the second sometime before the discussion. So we know who participates in the discussion, we will ask you some questions about yourself such as your age, gender, race and ethnicity. We will also ask you some questions about technology to figure out how you can connect with us for the discussion.

The biggest risk from being part of this study is a loss of confidentiality or privacy. Since these sessions will take place over Zoom, there is the chance that household members of other participants can hear the group discussion. If we invite you to a group discussion, we will be careful to maintain your confidentiality by asking you to use an alias (a fake name) in place of your real name, keeping your camera off, and by asking all participants to try their best to sit in a private location. There are no direct benefits to you if you participate in the study. However, you may feel a sense of satisfaction from your contribution to the testing of the guide. In the future, the guide may help other parents make choices their child's vaccinations.

- The discussion group will be recorded so that we can write down what everyone said. However, only your alias (fake name) will be linked with the recording. The audio recordings will be saved in a safe location on the Duke University server. Video recordings will be immediately and securely deleted.
- You will be paid \$50 for completing the whole study - \$5 each for completing each of the two surveys and \$40 for the focus group or interview. There is no cost to you for participating in the study.

- Being part of the study is completely voluntary. You can stop your participation at any time, and for any reason. Irrespective of your decision to participate, there will be no penalty or benefit to which you are entitled.
- Any information you provide to us up until the point when you choose to stop your participation will still be used in the study; however, we won't collect any new information after that. You may also choose to skip any question you feel uncomfortable answering.
- Study records that have your name or other personal information will be kept confidential as required by law. Federal privacy regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifiers in study records disclosed outside of Duke Health. For records shared outside of Duke Health, you will be assigned a unique number. The key that links your personal information to the unique number will be kept on a secure Duke server.
- Your study records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from Duke Health's Institutional Review Board, or other relevant groups.
- Results of this study may be presented at meetings or in publications, but your or your child's name will not be used. Any information that we publish will describe the participants on the whole, and not individually. For example, when we describe the age of the participants, we will only describe the average age across all participants and not your age separately.
- A description of this study will be available on <http://www.ClinicalTrials.gov>. When the study is completed, the Web site will include a summary of the results. This Web site will not include information that can identify you. You can search this Web site at any time.

### **Study contact information**

If you have questions about the study or any of the information in this document, please contact Dr. Lavanya Vasudevan via phone at 919-613-1423 or via email at [lavanya.vasudevan@duke.edu](mailto:lavanya.vasudevan@duke.edu). If you have any concerns about the study or your rights as a research participant, please contact the Duke University Health System Institutional Review Board via phone at 919-668- 5111 or online at <https://irb.duhs.duke.edu/contact-us>