

Consent to Participate in Research

Study Title: Using a computer game to teach American Indian youth positive coping skills.
(Listed in IRBNet as “Using Augmented Reality to Gamify a Universal Social Emotional Learning Intervention in Low-infrastructure Environments”)

Principal Investigators: Morgan Vigil-Hayes, PhD PI; Ann Futterman Collier, PhD co-PI

You are being asked to allow your child to participate in a research study. Your child’s participation in this research study is voluntary and your child does not have to participate. This document contains important information about this study and what to expect if you decide to allow your child to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to allow your child to participate.

Why is this study being done? We are developing a smartphone game called ARORA CARE (Augmented Reality Over Remote Access) for Native American youth. The goal of this game is to teach youth how to cope in a positive way, such as by asking friends for help or thinking about how others feel. We hope the game will be fun and something the youth enjoy doing.

We would like a group of children of all ages (12 to 18) to tell us what they like and don’t like about the game as we develop it. The research involves us recording what youth tell us what they think of the game, and what they learn from playing the game. We will ask about 20 youth to meet with us individually or in small groups to trial ARORA CARE and give us feedback.

What will happen if your child takes part in this study? He or she will meet with us once for 4 hours. We will show him/her the app and ask him/her to try it, and then give us feedback.

The game that your child will be playing uses butterfly characters to help encourage them to be aware of their feelings, their surroundings, and the people around them. Activities include breathing exercises, guided meditation, and walking while being aware of all the physical senses and feelings that are experienced during the walk. Activities also include sharing positive encouragement with other players, catching butterfly characters in the real world, and helping others catch butterfly characters that can be shared. Your child will be able to do parts of the game by themselves, but some parts of the game will require them to talk to other kids. Research activities will include meditation as well as walking.

Dr. Vigil-Hayes will bring smartphones to the meeting so that the children can try it out on our phone. Therefore, your child will not need to have a smartphone to take part in this study. Smartphones will be returned to Dr. Vigil-Hayes at the end of the meeting. The meetings may be audio recorded so that we have a record of what was said. Your child will also be asked to fill out six brief questions (such as age, school level), as well as 15 brief questions about his/her mood and stress. At the end of the software testing period, your child will be asked six questions that

ask them to reflect on their experience with the ARORA game and 15 brief questions about their mood and stress. In a group interview session, your child will be asked to reflect on their experience with their game, what they found useful and fun, and what they liked and did not like. These group interviews will be broken up into two age groups: 12-14 year olds and 15-18 year olds. everyone will be asked to keep all things discussed private and not disclose them to others after the session is concluded. However, your child's confidentiality cannot be guaranteed in a group setting.

What are the risks and/or discomforts your child might experience if he/she takes part in this study? There are no anticipated risks associated with participating in the software testing research. Software testers may be identifiable as research participants to other software testers. Even though their names may not be said in the focus group audio recordings, their identities may be known to the researchers. We will only present results of the overall findings; we will not identify your child individually. The audio recordings will not be used in any publications or future presentations. We note that younger children might feel tired or fatigued after testing the software and answering survey questions before and after the software testing period.

Are there any benefits for your child (or for others) if we choose to have him/her take part in this research study? Your child may or may not benefit directly as a result of participating in this study. One possible benefit is that your child will help us develop a game for American Indian youth that will be fun and useful for emotional health. Another possible benefit is that participants sometimes get to know about themselves when completing questionnaires.

What other choices does my child have if he/she does not take part in the study?

You may choose not to have your child participate in this study without penalty or loss of benefits to which you are otherwise entitled.

Will there be any cost to my child for taking part in this study? There is no cost to the software testers for participating in the study. We will provide all participants with a parking pass if they come to NAU for any meetings.

Will my child be paid to take part in this study? All participants will be paid \$25 after meeting with us.

Will my child's study-related information be kept confidential? Your child's name will not be placed on any of the questionnaire or stated in the audio recording. Your child's responses will be assigned a code number. The list connecting your child's name to this code will be kept in an encrypted and password protected file. Only the research team will have access to the file. When the study is completed and the data have been analyzed, the list will be destroyed. Only

the principal investigators will have access to the list that identifies your name; these will be kept in a locked file cabinet in one of their offices.

With your permission, we would like to audiotape your child's interview so that we can make an accurate transcript. Once we have made the transcript, we will erase the recordings.

Because of the nature of the data, it may be possible to deduce your child's identity; however, there will be no attempt to do so and your child's data will be reported in a way that will not identify them.

Your child will not be identified in any report or publication of this study. Even though we will tell all participants in the study that the comments made during the focus group should be kept confidential, it is possible that participants may repeat comments outside the group.

Information collected about your child will not be used or shared for future research studies.

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your child's participation in this study may be disclosed if required by state law. Also, your child's records may be reviewed by the following groups:

- Office for Human Research Protections or other federal, state, or international regulatory agencies
- Northern Arizona University Institutional Review Board
- The sponsor supporting the study (National Institutes of Health), their agents or study monitors
- Northern Arizona University Southwest Health Equity Research Center, their agents or study monitors

Who can you call if you have any questions? If you have any questions about your child taking part in this study or if you feel your child may have suffered a research related injury, you can call the Principal Investigator, Dr. Vigil-Hayes, at: 928-523-4863 or Morgan.Vigil-Hayes@nau.edu.

For questions about your child's rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Research Protection Program at 928-523-9551 or online at <http://nau.edu/Research/Compliance/Human-Research/Welcome/>.

If your child is injured as a result of participating in this study or for questions about a study-related injury, you may contact the office of Human Research Compliance at 928-523-9551.



An Institutional Review Board responsible for human subjects research at Northern Arizona University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

National Institutes of Health (NIH) Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality (CoC). This certificate protects your child by preventing researchers from sharing their identity with any Federal or State representatives should data be requested such as by a subpoena. It's important to remember that you and your family members must continue to actively protect your own privacy. For example, if you voluntarily give your written consent to someone like a lawyer or insurer to receive your child's research information, then researchers may not use the CoC to withhold it. Please also note that researchers are not prevented from the voluntary disclosure to report issues such as child abuse or report to prevent a threat to the safety of self or others. The Information we obtain during this study will be treated as confidential, as permitted by both Tribal and US Federal law. This certificate does not supersede Tribal Law and when on Tribal Land, Tribal law will govern.

Clinical Trial

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. 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.

AGREEMENT TO PARTICIPATE

I have read (or someone has read to me) this form, and I am aware that I am being asked to allow my child to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I affirm that I am at least 18 years of age and agree to give permission for my child to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of parent/LAR	Signature of parent/LAR	Date
Printed name of subject	Relationship to subject	Date



AGREEMENT TO BE AUDIORECORDED

Parental/LAR Signature: _____ Date: _____