INDIANA UNIVERSITY STUDY INFORMATION SHEET FOR RESEARCH

Pilot Randomized Control Trial of Cope 360 for Caregivers of Children with Cancer
Protocol#11097
National Cancer Institute

About this research
You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future. This form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this study is voluntary.
You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with IU School of Medicine or Riley Hospital for Children.

Why is this study being done?
The Cope 360 app was designed to support caregivers of children with cancer with symptom tracking, and medication management, and emergency preparedness. The purpose of this study is to find out if using the Cope 360 app improves how caregivers feel about their role.

You were selected as a possible participant because you are a caregiver of a child with cancer. The study is being conducted by Emily Mueller, MD, Riley Hospital for Children. It is funded by the National Cancer Institute within the National Institutes of Health.

What will happen during the study?
If you agree to be in the study, you will do the following things:

We will collect demographic information from you such as your age, education, gender, race, income, prior experience/exposure/awareness with computer or health technology, and your contact information. We will also ask for basic information about your child's cancer diagnosis including type of cancer, date of diagnosis, and type of treatment protocol.

You will then be randomly placed in a group that is either (1) the experimental group given the Cope 360 app and standard education or (2) the control group that is not given the app and given standard education. All participants will be asked to complete a survey sent to your email or completed over the phone at 1, 3 and 6 months.

If you are given the app, you will be asked to download it onto your personal smartphone and use it for a 6-month period. Information about the use of the app (such as logging a symptom or any error messages) is transmitted to the app developer and stored on a secure server for the researchers to look at. The app does not collect GPS location information. We ask that you delete the app from your phone at the conclusion of the study. If you are given the app, you may be asked to participate in a phone interview.

Any interviews will be audio recorded for accurate information gathering, and we may take photos or video. You will have the option to tell us you do not want photos or video taken.

What are the risks and benefits of taking part in this study?

The risks of participating in this research are loss of confidentiality and feeling uncomfortable answering questions or having audio or video taken. You can choose not to have video taken, and do not have to answer any questions that you do not want to. The information you enter into the app and the audio/video recorded during the interviews is password protected and stored using HIPPA compliant data security measures. We will not ask for any medical information about yourself or your child during the interviews, but you could self-disclose this information through some of the questions asked.

We don't expect you to receive any direct benefit from taking part in this study, but we hope to learn things which will help others in the future.

How will my information be protected?

All research includes at least a small risk of loss of confidentiality. Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be and databases in which results may be stored. All study data will be kept in a locked file cabinet and stored on a secured and encrypted server. Only the study team will have access to study data.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, and any state or federal agencies who may need to access your research records (as allowed by law). State and federal agencies may include the National Cancer Institute (NCI), the National Institute of Health, and Office for Human Research Protections.

Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it.

Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency

Will my information be used for future research?

Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

Will I be paid for participation?

You will receive a $5 gift card for completing the baseline assessment at enrollment, a $10 gift card for completing the 1-month survey, a $20 for the 3-month survey, and $40 for the 6-month survey. Interviews will be done with some caregivers in the experimental group at 6-months; those caregivers will receive an additional $20 for completing the interview.

Who should I call with questions or problems?

For questions about the study, contact Emily Mueller, MD at 317-944-0983 or email the study team at pedscncr@iu.edu.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.