

Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx*). Do not return the completed form to this address.

OMB Number: 0925-XXXX
OMB Expiration Date: TBD

Interactive Informed Consent for Pediatric Clinical Trials

Alan R. Tait, Ph.D., Terri Voepel-Lewis, M.S.N., R.N.
Department of Anesthesiology

This study is supported by the National Institutes of Health
Oral script for Informed Consent

You are being asked to participate in a **research study**. Some studies have shown that parents and children have trouble understanding information given to them about clinical research studies. We are trying to evaluate a new interactive computer-based program that presents information to parents and children about clinical research studies. The overall purpose of this study is to improve the way we give research information.

If you and/or child agree to participate in this study, we will ask you a few questions about your basic understanding of research studies. You will then be randomized to receive information describing a “pretend” study about asthma, using either standard written information or an interactive computer program. We are **NOT actually asking you to take part in the asthma study, but want you to think about the information as if it were real.** We only wish to find out your understanding of the information provided. If you receive the information using the computer program we will be available to answer questions or help you navigate through the computer program. After you go through the information, we will ask you some more questions about your understanding of the information and your thoughts on the presentation.

The decision to participate in this study is completely **voluntary**. If you decide later that you no longer wish to be in the study you may withdraw at any time without penalty.

You will probably need 30-45 minutes to take part, and you will be given a gift card for \$10 after you complete the study.

All information that we obtain will be anonymous so that your privacy will be maintained. Your name or that of your child, if appropriate, will not be recorded in the database. Data will be stored in a secure database and can only be viewed by members of the study team. Your name will not appear in any publications that may result from this study.

If you have any questions concerning the research project you should feel free to contact the principal investigator Dr. Tait at (734) 763-8128., 7433 Medical Science I Bldg. If you have concerns about your rights as a research participant or concerns about your experience in the project you may contact the University of Michigan Medical School Institutional Review Board (IRBMED), 2800 Plymouth Rd, Building 200, Rm 2086Ann Arbor MI 48109-2800Telephone: 734-763-4768, Fax: 734-615-1622

e-mail: irbmed@umich.edu