CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

STUDY TITLE: Randomized Controlled Trial of a Patient Activation Tool in Pediatric Appendicitis

PRINCIPAL INVESTIGATOR: Katherine Deans, MD

CONTACT TELEPHONE NUMBER: 614-722-0742

SUBJECT'S NAME: _____ DATE OF BIRTH: _____

NOTE: The words "you" and "your" are used in this consent form. These words refer to the study volunteer whether a child or an adult.

1) INTRODUCTION

We invite you to be in this research study because we want to know if an interactive patient activation tool can improve decision making and patient centered outcomes in patients with appendicitis and their parents/legal guardians.

Participation is voluntary. Using this form as a guide, we will explain the study to you. If you have any questions about the study, please ask. Once you understand this study, we will ask you to decide whether you would like to participate or not. By signing this form, you agree to be in this study. If you do not want to be involved with this study, all regular and standard medical care will still be available to you here or at another institution. You also have the right to leave this study at any time, even if you agree to join now.

If this study involves a child between 9 and 18 years of age, the child will receive an explanation of the study in a separate form, called an Assent form. If they agree to be in the study, they will be asked to sign this form.

You will be given a signed and dated copy of the consent and the assent form.

2) WHY ARE WE DOING THIS RESEARCH STUDY?

This is a study comparing the usual way of talking to patients about appendicitis and using an interactive tool (in this case, an iPad®) to talk to patients about appendicitis. There are currently no interactive tools being used with children and their parents/legal guardians that help them make informed decisions about appendicitis. Our goal is to find out if this interactive tool can "activate" patients and families. This means that the tool can help improve making decisions and patient centered outcomes like confidence in the decision you and your parent/legal guardian made.

3) WHERE WILL THE STUDY BE DONE AND HOW MANY SUBJECTS WILL TAKE PART?

This study will be done at Nationwide Children's Hospital and we hope to enroll 200 total participants; 100 in each group.

4) WHAT WILL HAPPEN DURING THE STUDY AND HOW LONG WILL IT LAST?

This study is randomized. Randomized means that each subject will be picked by chance, like tossing a coin or drawing straws, to receive either the usual way of talking to patients about appendicitis, or using an interactive tool to talk to patients about appendicitis. Each subject has a 50% (e.g. 50/50; 1 in 2) chance of receiving the usual talk and a 50% chance of receiving the interactive talk.

This study is also blinded. Blinded means that the Principal Investigator and the surgeons will not know who is receiving the interactive talk or the usual talk.

We will follow-up with your parent/legal guardian once a year for at least three years to see how you are doing and answer any questions you or your parent/legal guardian may have.

Talking about appendicitis

Once you are randomized to either the usual talk or the interactive talk, a physician research member will come into the room and they will talk to you about appendicitis and treatment choices. You and your family can ask the physician research member or the surgical team any questions before making a decision.

When you and your family have made a decision, the physician research member will call the surgeon so they can discuss the care plan with you and your family. You and your family will also answer questions on a tablet about: appendicitis, how prepared and confident you and your family are about making the decision, and if it was hard to make a decision.

Hospital Admission

You will be admitted to the hospital and receive care according to your treatment choice.

Before discharge, you and your family will complete another set of questionnaires that measure: your quality of life (QOL), satisfaction of care received, confidence in making the decision and any regrets with the decision. We will also ask your parents some questions about education, income level and reasons for the treatment choice they made.

2-14 day phone calls

If you and/or your parent/legal guardian choose antibiotics, a research member will call your parent/legal guardian to see how you are doing 2 to 5 days and 10 to 14 days after you have left the hospital. We will also ask questions about any problems you have had since you left the hospital. This includes how many days you missed at school and your parent/legal guardian missed at work, and any problems related to appendicitis.

30 day follow-up

Based on you and your parent/legal guardian's preference, you will either return to NCH or a member of the research team will call or email your parent/legal guardian for a follow-up. You and your parent/legal guardian will complete another set of questionnaires that measure: your quality of life (QOL), confidence in making the decision, any regrets with the decision, satisfaction with the decision and care you received and facts about appendicitis.

We will also ask questions about any problems you have had since you left the hospital, how many days you missed at school and your parent/legal guardian missed at work and how much money they spent on things related to your appendicitis.

6 month phone call

A member of the research team will call your parent/legal guardian for a follow-up. We will ask questions about any problems you have had since the 30 day follow-up, how many additional days you missed at school and your parent/legal guardian missed at work and how much money they spent on things related to your appendicitis, if any. This should take no longer than 10 minutes

1, 2 and 3 year phone call

A member of the research team will call your parent/legal guardian for a follow-up. We will ask questions about any problems you have had since the last follow-up, how many additional days you missed at school and your parent/legal guardian missed at work and how much money they spent on things related to your appendicitis, if any.

You and your parent/legal guardian will complete the same quality of life and satisfaction with the decision survey at the 1 year phone call.

This should take no longer than 15 minutes

Optional annual phone call

With your permission, a member of the research team will call your parent/legal guardian for a follow-up. We will ask questions about any problems you have had since the 1 year follow-up, how many additional days you missed at school and your parent/legal guardian missed at work and how much money they spent on things related to your appendicitis, if any. This should take no longer than 10minutes

We may repeat this annual follow-up call until you turn 18.

☐ Check here if we may call your parent/legal guardian each year until you are 18.

If you will turn 18 before our three year follow-up, you will be asked to sign the informed consent used for the study. This informed consent will be mailed to you to sign so that we may continue to collect data up to 3 years after your initial hospital discharge.

5) WHAT ARE THE RISKS OF BEING IN THIS STUDY?

We believe that there is very little chance that bad things will happen as a result of being in this study.

Usual Talk
There are no increased risks to being randomized in the usual talk group. However, it is possible that you could feel upset when answering questions from the surveys, but it may be more likely that you find the questions or feedback process a little boring. If you do find any of the questions upsetting or don't want to answer a question, you don't have to, and the study coordinator will be available to discuss this with you further.

Interactive Talk
Potential risks may include increases in decisional conflict or regret based on being activated and receiving information that might lead to more stress about the decision, or may lead to a decision you or your family may not have made before viewing the interactive tool.

It is also possible that you could feel upset when answering questions from the surveys, but it may be more likely that you find the questions or feedback process a little boring. If you do find any of the questions upsetting or don't want to answer a question, you don't have to, and the study coordinator will be available to discuss this with you further.

It is important that you give the study staff a complete medical history. Not giving them this information or not completely following the directions of the study could harm you.

There may be other risks of being in this research study that are not known at this time.

6) ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

Usual Talk
There are no direct benefits to patients randomized to the usual surgical talk but information obtained may help others.

Potential benefits of this research include determining that patient-caregiver activation for pediatric appendicitis improves decision making and patient centered outcomes.

Interactive Talk
Patients in similar studies who have received something similar to the interactive tool have experienced some of the following benefits:

- They have had improved understanding of their health problem and the possible treatment options, so they have had more confidence making a decision
- Because they made decisions with more confidence, they experienced less conflict or regret about the decision
- They reported having overall better satisfaction with their health care.

7) WHAT ARE THE COSTS AND REIMBURSEMENTS?

All costs related to the research parts of this study will be covered by the research team. However, the parts of the study that would be done for routine clinical care will be billed to you and to your

insurance company or third party payer. You may have to pay any costs that the insurance company or third party payer does not pay. The study team will discuss these costs with you.

To thank you and your parent/legal guardian for participating, your parent/legal guardian will receive a $25 VISA® gift card for your 30 day, $30 for your 6 month and $35 for your 1 year follow-up. A parking voucher will be provided if you come in for your 30 day follow-up. A $50 VISA® gift card will be given after completing the 2 year and 3 year follow-up phone calls.

8) WHAT HAPPENS IF BEING IN THIS STUDY CAUSES INJURIES?

We believe that there is very little chance that injuries will happen as a result of being in this study.

9) WHAT HAPPENS IF I DO NOT FINISH THIS STUDY?

It is your choice to be in this study. You may decide to stop being in this study at any time. If you decide to stop being in this study you must call the Principal Investigator or the study coordinator to see if there are any medical issues about stopping. If you stop being in the study, there will not be a penalty or loss of benefits to which you are otherwise entitled.

If at any time the Principal Investigator believes that this study is not good for you, the study staff will contact you about stopping. If the study instructions are not followed, participation in the study may also be stopped. If unexpected medical problems come up, the Principal Investigator may decide to stop your participation in the study.

10) OTHER IMPORTANT INFORMATION

Being in more than one research study at the same time may cause injury. Please tell us if you are in any other research study so a decision can be made about being in more than one study at the same time. We may need to notify the other study team to see if you can participate in this study.

If your parent/legal guardian is an employee of Nationwide Children's Hospital or the Research Institute at Nationwide Children's Hospital, their job or performance appraisal will not be affected in any way if you decline to participate or withdraw your consent to participate in this study.

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 you. At most, the Website will include a summary of the results. You can search this Web site at any time.

The final study results will not be shared with you individually. However, at some time, a final study summary will be available on the ClinicalTrials.Gov (http://clinicaltrials.gov) website.

Nationwide Children's Hospital is a teaching hospital and we are committed to doing research. Doing research will enable us to learn and provide the best care for our patients and families. You may be asked to participate in other research studies in the future. You have the right to decide to participate or decline to participate in any future studies. We will not share your contact information with researchers outside Nationwide Children's Hospital.

11) HOW WILL MY STUDY INFORMATION BE KEPT PRIVATE?

Information collected for this study may include information that can identify you. This is called "protected health information" or PHI. By agreeing to be in this study, you are giving permission to Dr. Katherine Deans and the study staff to collect, use, and disclose your PHI for this research study unless otherwise allowed by applicable laws. Information collected is the property of Nationwide Children's Hospital.

The reason why this PHI is collected, and what information will be used is listed below. The PHI will only be shared with the groups listed, but if you have a bad outcome or adverse event from being in this study, the Principal Investigator and staff or other health care providers may need to look at your entire medical records. In the event of any publication regarding this study, your identity will not be revealed.

The PHI collected or created under this research study will be used or disclosed as needed until the end of the study. The records of this study will be kept for an indefinite period of time and your authorization to use or disclose your PHI will not expire.

PHI that may be used or disclosed: Names (individual, employer, relatives, etc.); Address (including city, state, zipcode and county); Telephone/Fax Numbers; Dates (except for years); Birth Date; Admission Date; Discharge Date; Date of Death; E-mail Addresses/URLs; Medical Record Numbers; Any other unique identifying number, characteristic, or code

People or Companies authorized to use, disclose, and receive PHI collected or created by this research study:

- PI and study staff
- The Nationwide Children's Hospital Institutional Review Board (the committee that reviews all human subject research)
- Nationwide Children's Hospital internal auditors
- The Office for Human Research Protections (OHRP) (the federal government office that oversees human subject research)
- Your insurance company (if charges are billed to insurance)

Because of the need to give information to these people, absolute confidentiality cannot be guaranteed. Information given to these people may no longer be protected by federal privacy rules.

Reason(s) why the use or disclosure is being made:
PHI is needed to locate your medical charts and obtain the information we will be collecting for the study. Also, we may need to contact you in the future to follow-up on your health status.

You may decide not to authorize the use and disclosure of your PHI. However, if it is needed for this study, you will not be able to be in this study. If you agree to be in this study and later decide to withdraw your participation, you may withdraw your authorization to use your PHI. This request must be made in writing to the Principal Investigator at Nationwide Children's Hospital 700 Children's Drive

Suite JW4914, Columbus, OH 43205. If you withdraw your authorization, no new PHI may be collected and the PHI already collected may not be used unless it has already been used or is needed to complete the study analysis and reports.

As stated above, your PHI may be used or disclosed for future research purposes, and as part of such future research purposes, your PHI may even be disclosed to people or entities that are not listed above, such as other researchers not involved with this study, government agencies, research foundations, or pharmaceutical or device companies sponsoring future research. This future research may be related to your medical problem, but it may be related to other diseases or conditions as well. Any future research projects, however, will be reviewed and approved by an Institutional Review Board, which protects the rights, welfare, and safety of human research subjects.

I agree to allow my PHI to be stored and used for future research as described above: (initial your choice)

_____ YES _____ NO

12) WHOM SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have questions about anything while on this study or you have been injured by the research, you may contact a research member at 614-722-0742, Monday – Friday, between 8am -5 pm. After hours, you can call the Nationwide Children's Hospital Surgeon's Office at 614-722-3900 and ask for the surgeon on call.

If you have questions, concerns, or complaints about the research; if you have questions about your rights as a research volunteer; if you cannot reach the Principal Investigator; or if you want to call someone else - please call (614) 722-2708, Nationwide Children's Hospital Institutional Review Board, (IRB, the committee that reviews all research involving human subjects at Nationwide Children's Hospital).

Subject's Name _____Date of Birth_____

SUBJECT or SUBJECT'S PARENT OR PERSON AUTHORIZED TO CONSENT ON BEHALF OF THE CHILD (SUBJECT TO THE SUBJECT'S GENERAL MEDICAL CARE)

I have read this consent form and I have had an opportunity to ask questions about this research study. These questions have been answered to my satisfaction. If I have more questions about participating in this study or a research-related injury, I may contact the Principal Investigator. By signing this consent form, I certify that all health information I have given is true and correct to the best of my knowledge.

I have been given a copy of the Nationwide Children's Hospital Notice of Privacy Practices. If allowed by law, I understand that my right to any information that is created or collected by Nationwide Children's Hospital for this study can be temporarily suspended if necessary for the purposes of this research project. I also understand that my right to access to this information from this study will be reinstated upon completion of this research unless I have been told by the Principal Investigator that I will not receive study results.

I agree to participate in this study or I give permission for my child to participate in this study. I will be given a copy of this consent form with all the signatures for my own records.

CONSENT SIGNATURES

_____ _____
SUBJECT or SUBJECT'S LEGAL REPRESENTATIVE **DATE & TIME AM/PM**

_____ _____
SUBJECT or SUBJECT'S LEGAL REPRESENTATIVE **DATE & TIME AM/PM**

Permission of the second parent not obtained because (select all that apply):
__X___ Not required by the IRB (risk level 1 or 2).
_____ Other parent is deceased.
_____ Other parent is unknown.
_____ Other parent is not reasonably available.
_____ Only one parent has legal responsibility for the care and custody of subject.

_____ _____
PERSON OBTAINING CONSENT **DATE & TIME AM/PM**

I certify that I have explained the research, its purposes, and the procedures to the subject or the subject's legal representatives before requesting their signatures.