STUDY INFORMED CONSENT STATEMENT FOR RESEARCH

Engaging Families to Improve the Care of Patients With Hypospadias

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Engaging Families to Improve the Care of Patients with Hypospadias (# 1511846401)

Decision Aid Acceptability – Pilot Testing by Parents

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 consent 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 in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with Riley or the IU School of Medicine.

WHY IS THIS STUDY BEING DONE?
The purpose of the overall research project is to develop a "decision aid" tool for parents of sons with hypospadias (an abnormal opening of the pee hole on the underside of the penis) to help them with decision-making about surgery. The decision aid tool that we are studying is a website. You were selected as a possible participant because you are at least 18 years old and your son has been diagnosed with hypospadias by a medical provider and is scheduled to see a Riley Urologist.

The study is being conducted by Martin Kaefer, MD, Professor of Urology at the Indiana University School of Medicine and Katherine H. Chan, MD, MPH, Associate Professor, Urology at University of North Carolina. It is funded by the National Institute of Diabetes and Digestive and Kidney Diseases.

HOW MANY PEOPLE WILL TAKE PART?
If you agree to participate, you will be one of about 10 parents providing feedback on this decision aid website prototype.

WHAT WILL HAPPEN DURING THE STUDY?
This study involves collection of information about you or from you. If you agree to be in the study, you will do the following things:

1. Answer questions about the website, about your son's health related to hypospadias, and your experience with making a decision: You may answer questions at four time points, two times before your visit with the Riley urologist, and two times after, if the urologist confirms the diagnosis of hypospadias. You will answer the questions over the phone with a trained research assistant. We think that it will take between 5-20 minutes each time you answer questions.

- Time point 1, before urology appointment
- Time point 2, before urology appointment, about a week after time point 1
- Time point 3, after urology appointment (ideally, within 1-2 days of appointment)

- Time point 4, 3 months after surgery, or if no surgery, 3 months after urology appointment

Please note that we will withdraw (remove) you from the study if you are unable to complete the time point 2 questions before the urology appointment, or if you do not attend the appointment. Also, we will withdraw you from the study after the urology appointment if the urologist decides that your son does not have hypospadias, or we may withdraw you if the urologist decides that your son has very mild hypospadias. If we withdraw you from the study, we will call you or send you a text or email to let you know.

The questions will cover the following topics:

- your experience with your son's hypospadias, including your process for making a decision about whether or not your son will have surgery
- your thoughts about the decision aid website and what you remember
- if you used the website in any way during the visit with the urologist
- if and how the website was useful in your decision making process
- what recommendations that doctors made to you about surgery or not
- the decision that you made for your son and any concerns, regrets, or things you wish you would have known but didn't
- common demographic questions about you, for example, your race and education level.

We may record any phone interviews so that we can have them transcribed (typed out) so that we can look for common themes.

2. View the hypospadias decision aid website: After you answer the questions for time point 1, we will send you a link with a unique username and password so that you can look around the website at your own convenience between the data collection time points, especially between the first and second phone calls. The information has general information about hypospadias and making a decision about surgery but it does not contain any identifiable patient information. (There are no photos or names of real patients.) As you move around the website, we will use software to track how you move through the site, e.g. how long you spend on each page and the order you move through the pages.

3. Allow us to use your son's medical information that we collected from your son's electronic medical records at Riley. In order to identify parents of sons with hypospadias and approach about reviewing our decision aid website, we collected information including your son's name, date of birth, the date that he saw the urologist, the name of the urologist and/or surgeon, your son's diagnosis of hypospadias, whether or not the urologist recommended surgery and notes about your son's hypospadias, the date that your son may be scheduled for surgery, and demographics about your son such as race, gender and ethnicity, insurance type, and the contact information we have for you. We may also collect and use the following information from your son's medical record for this research:

any additional surgeries related to hypospadias and doctor notes from urology visits about hypospadias.

4. Receive study reminders: We will remind you about upcoming data collection time points by sending an email or text, or by phone call, depending on your preference. We will also remind you to view the decision aid website between time points 1 and 2.

WHAT ARE THE RISKS OF TAKING PART AND HOW WILL MY INFORMATION BE PROTECTED?

There is a small risk of possible loss of confidentiality. This means that someone outside of the research team may see your answers and possibly information about your son. We will do everything possible to protect your information. 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. No information which could identify you will be shared in publications about this study. Audio recordings will only be accessible to the research team and the person doing the transcription (typing up the interview) and the recordings will be destroyed when the research is complete and we are allowed by law to destroy study records.

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, the National Institute of Diabetes and Digestive and Kidney Diseases, and any state or federal agencies who may need to access your medical and/or research records (as allowed by law). State and federal agencies may include the Office for Human Research Protections (OHRP) for federally-funded research and the National Institutes of Health (NIH).

For the protection of your privacy, this research is covered by a 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;

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

We don't know if you will receive any benefit from taking part in this study, but we hope that the website will help parents and physicians to make better decisions about repair surgery.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information 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.

We may ask for your permission to contact you for future activities that are part of this research to create a decision aid website for parents.

WILL I BE PAID FOR PARTICIPATATION?

You will be paid in gift cards for completing questions at each time point:

- Time point 1: $20
- Time point 2: $20
- Time point 3: $40
- Time point 4: $20

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study, contact the researcher, Martin Kaefer, MD, at Indiana University at 318-948-1021. You may also contact Dr. Katherine Chan at University of North Carolina at 919-843-9330. For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

CAN I WITHDRAW FROM THE STUDY?

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. If you decide to withdraw, you just need to tell the research assistant that you no longer want to participate.

[research staff to document verbal consent in secure database]