INDIANA UNIVERSITY STUDY INFORMATION SHEET AND AUTHORIZATION FOR RESEARCH

Systematic Pediatric Assessment of Rome Criteria (SPARC)
Principal Investigator: William Bennett MD
IRB Protocol # 1811325201

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 Study Information Sheet and Authorization 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 Eskenazi Health.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to improve the process of finding and treating gastrointestinal (GI) problems, such pain and other issues related to the stomach and small and large intestines. You were selected as a possible participant because you (parent), you and your child, or your child recently completed the *Gastrointestinal (GI) Symptom Survey* prior to or at a recent visit to their pediatric primary care provider. This study is being conducted by Dr. William Bennett at Indiana University School of Medicine. 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 600 participants taking part in this part of the study.

WHAT WILL HAPPEN DURING THE STUDY?
If you agree to be in the study, you will answer survey questions over the phone or online.

The parent, the parent and patient, or the patient (if age 10-17) will be asked answer similar symptom questions to those asked in the *Gastrointestinal (GI) Symptom Survey* as well a few extra questions related to satisfaction and potentially parent concern.

It usually takes about 5 minutes to answer the survey questions. We ask that participants answer these phone survey questions at 1 month, 3 months, 6 months, and 12 months out from your recent appointment.

To see who qualified for the survey, we accessed information about you/your child's recent visit to the pediatrician. With your permission, we will keep this information to help us learn if something at the visit helped you or the pediatrician to better find and treat GI problems.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?
If you choose to be part of this study, there are two risks:

1. Answering questions could make you feel uncomfortable. If you do not want to answer a question, please let the researcher know and we will skip it.

2. It is possible that someone who is not part of the research team could see your answers to the questions that I will ask you. This is called a "loss of confidentiality". To prevent this, we will keep all of that information in a secure database that only study team members at Indiana University can enter through usernames and passwords. We will not share your answers with anyone outside of the research team.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?
There will probably be no direct benefit to you for participating in this study but we hope that your answers will help us to learn how doctors can do a better job of screening and treating GI issues.

HOW WILL MY INFORMATION BE PROTECTED?
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.

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 (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) and the National Institute of Diabetes and Digestive and Kidney Diseases, who may need to access the research records.

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.

A description of this clinical trial will be available on ClinicalTrials.gov. 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 website at any time.

WILL I BE PAID FOR PARTICIPATION?
Participants have the opportunity to receive a total of $75 for participation as a thank you for time spent.

Payments will be made to participants in the form of an electronic gift card. Participants will be paid:

- $25 for completing study enrollment and the 1 month phone survey
- $10 for each phone survey completed at the 3, 6, and 12 month timepoints
- $20 bonus after the 12-month phone survey for participants who complete all requested timepoints

Each participant unit (the parent or parents, the parent and patient, or the patient) will receive one payment for each time point. For example, if a patient and parent complete the enrollment and one month survey together they will receive an e gift card for $25 to share.

WILL IT COST ME ANYTHING TO PARTICIPATE?
There is no cost to you for taking part in this study.

HOW WILL MY INFORMATION BE USED?
The study team will collect information about your child from their medical records. This information, some of which may identify them, may be used for research-related purposes. This may include making sure your child meets the criteria to be in this study, gathering information about your child's medical history to include in the research data, checking on your child's health in the future to help answer our research question, or to inspect and/or copy your research records for quality assurance and data analysis.

I understand the information listed below will be released and used for this research study:

- Name, birthdate, race/ethnicity, and Eskenazi medical record number
- Name, address, and phone number
- The date of the recent appointment and the name of the Eskenazi pediatrician
- Answers to questions in clinic about gastrointestinal symptoms
- Notes that your doctors made about talking to you about gastrointestinal symptoms
- Medical records for other visits, hospitalizations, images, tests, and medication for GI issues
- Answers from this phone survey

If you agree to participate, you authorize the following to disclose your medical record information:

- Indiana University Health
- Indiana University Health Physicians
- IUMG – Primary Care Physicians
- Eskenazi Health
- Eskenazi Health Physicians
- Indiana Network for Patient Care (INPC)

The following individuals and organizations may receive or use your identifiable health information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- US or foreign governments or agencies as required by law
- State or Federal agencies with research oversight responsibilities, including but not limited to:
    - National Institute of Diabetes and Digestive and Kidney Diseases
    - National Institutes of Health (NIH)
    - Office for Human Research Protections (OHRP)

Information collected for this study may be used for other research studies or shared with other researchers for future research. If this happens, information that could identify you, such as your name and other identifiers, will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

A description of this clinical trial will be available on 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 website at any time.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study, contact the researcher, you can contact Dr. Dr. William Bennet during business hours, at 317-974-3774.

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.

WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to participate in the study. Or, you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after agreeing to participate, it will not affect your usual medical care or treatment or relationship with Eskenazi Health.

If you change your mind and decide to leave the study in the future, please inform us about your desire to stop the study by calling the research number above.

If you choose to withdraw your authorization for use and disclosure of your protected health information, you must do so in writing by notifying:

William Bennett, MD
Indiana University Department of Pediatrics
Children's Health Services Research
410 West 10th Street, HS2000
Indianapolis, IN 46202

If you withdraw your authorization, you will not be able to continue in this study. However, even if you cancel this authorization, the research team, research sponsor(s), and/or the research organizations may still use information about you that was collected as part of the research project between the date you signed this document and the date you cancelled this authorization. This is to protect the quality of the research results. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed.

AGREEMENT TO BE CONTACTED BY EMAIL

We would like to communicate with you about this study by email. We use email to send your electronic gift card after completing study tasks, remind you of upcoming interview times, and possibly send secure survey links to interview questions if you choose to complete online.

Email is not a secure method of communication. The information sent over email, which may include sensitive or personal information, such as protected health information, could be accessed or read by someone other than you. If you would like us to communicate with you email, please initial the lines below and provide the email address(es) you would like us to use.

I authorize the researchers to send me emails related to this research study: "YES" or "No"

Email address for this communication: _____

You can still participate in this study even if you do not want us to contact you email.