Cooper University Hospital

# INFORMED CONSENT AND HIPAA AUTHORIZATION TO PERMIT THE USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH PURPOSES

TITLE OF STUDY: *Standardized Yoga & Meditation Program for Stress Reduction for Adolescents with Irritable Bowel Syndrome*

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DEPARTMENT(S): Pediatric Gastroenterology, Psychiatry

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What does the research study involve?
Your child is being invited to take part in a research study. This form is part of an informed consent process. It will give you information to help you decide if you want your child to volunteer for this research study. Volunteer means you choose to take part. Your child does not have to take part in this study to receive treatment at Cooper Hospital. The study doctor and her staff will discuss with you what is involved in this research study. If you decide you want your child to take part, you and the study doctor or a member of the study team will sign this consent form. You will receive a copy of this consent form to keep. If you have questions at any time during the research study, you should feel free to call any of the doctors listed above and ask your questions until you receive answers that satisfy you.

What is the purpose of this research study?
The following is a short summary of this study to help you decide whether to permit your child to be a part of this study. The purpose of this study is to determine if yoga can help alleviate the symptoms associated with Irritable Bowel Syndrome. If you decide to allow your child to participate, he or she will be asked to fill out the Screen for Child Anxiety Related Disorders, Pediatric Quality of Life Inventory and Children Somatic Symptoms Inventory. These assessments range from 20-41 questions, where you will be asked to rank your answer on a sliding scale. The questions are no more than 1 sentence each. In addition, your child will participate in a brief 6-week, 2 times a week, online yoga course and a follow up phone call survey. This is different from standard of care in that these screening tools and a yoga intervention is not part of normal treatment. Standard of care includes routine doctor visits, taking necessary medication and any procedures that are needed. A total of 45 subjects will be enrolled in this study. Your child's participation in the study will last 6 weeks. You can ask all the questions you want before you decide.

What risks are there?
Your child will be answering questions associated with their symptoms. Some of the questions we will ask you are about sensitive issues. You do not have to answer those questions if you do not want to. In addition, they will be participating in a mild yoga routine. There is no expectation of injury.

What benefits are there?
Your child's participation in this study may result in alleviation of his/her pain/discomfort and symptoms associated with Irritable Bowel Syndrome. The knowledge gained from this study may benefit future IBS patients.

What are your alternatives (other choices) if you do not take part in this study?
The alternative is for your child to not take part in this study.

When can your participation be terminated by the investigator?
The investigator may terminate your participation in the study if your child is not able to complete the yoga modules.

Are there any other costs?
There are no costs to your child from participating in this study.

Will you be paid for participation?
Your child will not be paid for participation.

What will happen if you withdraw?
Tell the investigator via email if you want your child to withdraw from the study. Withdrawal from this study will not affect your child's care at Cooper Hospital or with Dr. Isola.

Will you be told about new information that might affect your decision to take part in this research?
During the study, you will be told if any new information is learned that could affect your child's willingness to stay in the study.

## USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH PURPOSES

Will your information be kept confidential?
The privacy regulations of a law passed by Congress became effective on April 14, 2003. The law is called the Health Insurance Portability and Accountability Act, HIPAA for short. The law gives subjects in research studies certain rights about their protected health information. Protected health information (PHI) is information about a person's physical or mental health that can be identified with or linked to that particular person. If you sign this form you are giving the investigators, their staff, and certain other people described in this form your permission to use your protected health information for this research study.

The information collected about your child for this study is called "protected health information" (PHI). It includes demographic information (e.g., your name, address, etc.), medical history, and your child's answers to the study questionnaires.

All of this information is being collected because your child is participating in this research study

Information about your child will also be collected from your medical records that are located in Cooper University Hospital's medical records department. The information that is collected will be used to decide if your child qualifies to participate in this research, to follow your treatment, and will be analyzed to answer the research questions. All the files and records created for this study will be stored in Dr. Kushnir's office at 755 Dorrance and Cooper Hospital in a locked cabinet or in a computer with a password.

To help maintain the confidentiality of your child's study records, your child will be assigned a subject number. All of your child's study related-information will have only his or her subject number. Identifying information, like your child name, address, and telephone number, will be linked to his or her subject number but will be kept separate from your child's study-related information. Your child's study documents will be stored in a locked file cabinet. The information from this study may be published in scientific journals or presented at scientific meetings but your child will not be personally identified in these publications and presentations.

By agreeing to participate, you are allowing the following people or groups to have access to the information described above (your child's PHI).

The research team, which includes the investigators listed on this form and other personnel involved in this specific study need to analyze the data.

Cooper's Institutional Review Board (IRB), a committee that reviews, approves, and monitors research involving human subjects may look at your study records.

All of these people and entities are obligated to protect your child's PHI.

You have the right to limit the use and sharing of your child's PHI, and you have the right to see your child's research study records and know who else is seeing them. You will not be allowed to see your child's health information that is created or collected during the course of the research. After the research is finished, however, you may see this information.

You are authorizing us to use and disclose your child's PHI indefinitely. You may revoke this authorization to use and share your child's PHI at any time by contacting the principal investigator, in writing, at the address on the front of this form. If you decide not to authorize the investigator to use and disclose your child's PHI or you revoke this authorization, your child will no longer be able to participate in this research study, and the use or sharing of future PHI will be stopped. However, the PHI that has already been collected may still be used.

Whom can you contact if you have a question?
If you have any questions about this research, you can contact the principal investigator at the number on the first page.

You should call the Chief Medical Officer or his representative at (856-342-3071) (a) if you have any questions about your rights as a research subject or your rights related to the research use of your PHI, (b) if you believe that you have not been told about all the risks, benefits, and alternative treatments, (c) if you believe that you are being forced to stay in this study when you do not want to, or (d) you have any complaints about the research.

You should also contact that person if you believe that you have not been adequately informed as to the risks, benefits, or alternative procedures of this research study, or that you are being pressured to participate in the study against your wishes.

If you have any questions about the research or your rights as a subject or any complaints about the research, you may also contact the Institutional Review Board (IRB) of the Cooper Health System. The IRB is responsible for protection of subjects participating in this research project. The address of the IRB is E&R Building, 401 Haddon Ave., Room 288, Camden, NJ 08103. The phone number is 856 757-7832.

CONSENT STATEMENT

Your child's participation and your decision to allow the use of your child's PHI are entirely voluntary. You do not have to participate or let us use your child's PHI. If you decide not to participate or not to let us use your child's PHI or you decide to have your child stop participating or to stop letting us use your child's PHI, it will not affect your treatment at Cooper University Hospital. Your doctors will continue to treat you the way they always have.

All of the above has been explained to me. All of my questions have been answered. I can ask questions that I have about the research or about the use and disclosure of my child's PHI at any time. My questions will be answered by one of the investigators listed on the first page of this form.

By verbally agreeing to this form, I agree to my participate in this study and I agree to the use and disclosure of my PHI for the purposes described above. A copy of this form will be given to me.