ORAL CONSENT SCRIPT

Hello. My name is Dr. Lily Barash and I am from Montefiore and would like to talk to you about a research study on hypnotherapy. We are studying the role of audio-recorded gut-hypnotherapy on sleep quality and abdominal pain in pediatric functional abdominal pain disorders including irritable bowel syndrome and functional abdominal pain-not otherwise specified. You/ your child are being asked to participate in this study because you have been identified as meeting the diagnostic criteria for irritable bowel syndrome or functional abdominal pain-not otherwise specified and have persistent symptoms. You do not have to participate, it is your choice. Your decision will not affect your rights or benefits or your access to care.

If you say yes, we will ask you to listen to audio-recorded hypnotherapy sessions over a 6-week time frame. You will be randomly assigned to either start hypnotherapy now or to wait 6 weeks before starting hypnotherapy.

Hypnotherapy creates a focused and absorbed state of attention where you are more receptive to new ideas. Clinical hypnotherapy involves a set of skills such as guided imagery that facilitate a focused state of attention called trance. This is a normal state that you may enter many times during the day, when you get really focused on something that you're concentrating on. Examples include driving without realizing how you got from point A to point B or getting so caught up in a film that time seemed to pass effortlessly. During trance, facilitated by hypnosis, openness to suggestions can be enhanced, senses heightened, mental absorption increased, and imagination activated in controlled manners that improve your health. In gut-hypnotherapy the focus is learning how to better control your gut function through a state of trance.

Hypnotherapy will be available in an audio-recorded format on a secure website. There will be a total of four 30-minute sessions over a 6-week time frame. There will also be shorter 10–15-minute daily sessions. Participants will do at least 5 daily sessions per week. Surveys will be administered after enrollment (22 minutes in length), prior to starting hypnotherapy in the group waiting 6 weeks to start, at 2-week intervals during the course (each 5 minutes in length), after the course (22 minutes in length), and 12 weeks after course completion (12 minutes in length). There will also be a question to rate your abdominal pain prior to each audio recording (1 minute). For those who wait 6 weeks before starting the course, you will receive an additional survey prior to starting the sessions.

You may be uncomfortable answering some questions. You do not have to answer all the questions and you may stop at any time. We do not think there are any physical risks related to participating in this research study. Hypnotherapy is very safe. There have been reports of headaches, mild and transient. The participant may decide whether to continue or not if they experience these symptoms.

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy.

You may or may not receive personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include improvement in abdominal pain, sleep quality, quality of life, and anxiety level. Participants may have positive feelings about being able to contribute to the future distribution of this treatment in children.

We will pay you for your participation in the study. Compensation will be awarded throughout the study. If you start hypnotherapy right away, you can earn 40 dollars for completion of the course. Money will be awarded in increments: you will receive 5 dollars after the completion of the baseline, 2-week, and 4-week surveys. You will receive an additional 10 dollars for completion of the 6-week survey and then an additional 15 dollars for completion of the follow-up survey 12-weeks after the course. If you wait to start hypnotherapy (control group), you can earn 45 dollars for completion of the course. You will receive 5 dollars for completing the baseline survey and 6-week survey, and then can receive the same compensation in the increments explained above while completing the hypnotherapy course. You will be awarded money for the portions of the trial you complete. We will ask you to complete a form for ClinCard, a website to activate a debit card for the study.

We will do our best to keep your information safe by using a special code. We do not plan to share the information from this study with other researchers. Your study information will be kept as long as it is useful for this research.

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. If you do not provide your verbal consent, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, social security number, medical record numbers, etc.

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research, if applicable
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

Future research:

- Information from this study may be used in future research studies by our study team.

There are several people and groups who may see your study information in order to make sure the study is being done correctly. This includes:

- the research team and staff who work with them
- groups that review research such as the Einstein IRB, and the Office for Human Research Protections

These people who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

If you change your mind and don't want your information used for the study anymore, you can call the person in charge of this study. Her name is Rachel Borlack and she can be reached at 646-847-8013. Or, you can call Einstein Institutional Review Board at 718-430-2253. They will let you know how to write to the Principal Investigator to let her you want to stop participating. Just remember, if we have already used your information for the study, the use of that information cannot be cancelled.

Do you have any questions? You may ask me now, or contact Rachel Borlack about your questions or problems with this study.

May I begin?

CONSENT TO PARTICIPATE

Printed name of participant		Date
Printed name of the person conducting the consent process	Signature	Date