

Study Title: Healthy Kids I-PAL

NCT #: NCT03297541

Document date: 08.24.2017



## **Consent Form for Study Involving Minimal Risk**

### ***Project I-PAL***

**Introduction:** I, \_\_\_\_\_, have been asked to allow my child, \_\_\_\_\_, to participate in Project I-PAL. Dr. Kihm and Dr. Staiano will be overseeing the study at Southeastern Louisiana University and have established the study to help youth and their families develop healthier lifestyles by providing them with unique opportunities to engage in physical activity. I have had the chance to speak with a staff member from Project I-PAL who has gone over the study with me.

**Purpose of the Study:** The purpose of the study is to observe whether children who participate in Project I-PAL can become more active and obtain a healthier lifestyle by engaging in different health assessments and exercise activities.

**Description of Procedures:** This study will be performed at the I-PAL lab on the Southeastern Louisiana University campus. My child will be asked to:

- Visit the lab twice a week, for a total of two hours each week, over the next 4 months.
- Have their height and weight measured at the beginning and end of the study.
- Fill out some surveys pertaining to their physical activity, food intake, mood, and other habits at the beginning and end of the study.
- Take part in health assessments and exercise activities using different exercise equipment and virtual games.

I have been given an opportunity to examine the study material related to the above mentioned procedures. Approximately 100 participants will be in this study.

**Risks and Discomforts:** This study does not involve major risks. However, my child may experience some physical pain and soreness when they first begin exercising. This is common for individuals who are inactive and then become active.

My child may also feel embarrassed from having their personal information collected such as weight, questions regarding their personal attributes, and their food intake. This risk is anticipated to be temporary and minimal.

**Benefits:** I understand that this study may or may not directly benefit my child, but the knowledge gained may be of benefit to others.

**Contact Persons:** For more information about this research, I can contact Dr. Kihm, at 985-549-5693 or Dr. Staiano at 225-763-2729.

For information regarding my child's rights as a research participant, I may contact the Chair of the Institutional Review Board at 985-549-2077.

**Confidentiality:** I understand that any information obtained as a result of my child's participation in this research will be kept as confidential as legally possible. In any publications that result from this research, neither my child's name nor any information from which they might be identified will be published without my consent.

**Voluntary Participation:** Participation in this study is voluntary. I understand that I may withdraw my child from this study at any time. Refusal to participate or withdrawal will involve no penalty or loss of benefits for me or my child. I have been given the opportunity to ask questions about the research, and I have received answers concerning areas I did not understand. Upon signing this form, I will receive a copy.

I willingly consent to my child's participation in this study.

---

Signature of Parent or Guardian

Date

---

Signature of Investigator or Investigator's Representative

Date

## **Verbal Assent Form for Study Involving Only Minimal Risk *Project I-PAL***

Per study protocol, verbal assent will be obtained from children younger than 10, or from participants with a low literacy level.

**Introduction:** \_\_\_\_\_, you have been asked to be in this research study, which has been explained to you by Project I-PAL staff.

**Purpose of the Study:** The purpose of this study is to gain information on how you can become more active and obtain a healthier lifestyle.

**Description of Procedures:** This study will be performed at the Project I-PAL lab on the Southeastern Campus. If you want to be in the study, you will be asked to:

- Visit the lab twice a week, for a total of two hours each week, over the next 4 months.
- Have your height and weight measured at the beginning and end of the study.
- Fill out some surveys about your physical activity, the foods you eat, how you feel, and other habits at the beginning and end of the study.
- Take part in health assessments and exercise activities using different exercise equipment and virtual games.

You do not have to answer all of the questions or take part in all of the activities if you do not feel comfortable.

**Discomforts:** Some of the questions will be difficult and you may not enjoy trying to answer them. You also may be a little sore when starting to exercise or you might get short of breath for a short time during exercises, but that will go away.

**Benefits** This study may or may not help you become healthier and more active. However, what we learn from the study may help other children.

**Confidentiality:** We promise that anything we learn about you in this study will be kept as secret as possible.

**Voluntary Participation:** You do not have to do this study. No one will be mad at you if you refuse to do this or if you decide to quit. You can now ask me any questions about the research, and all of your questions will be answered. If you do decide to participate, you will receive a copy of this form after someone from the I-PAL team has signed it. By having an I-PAL team member sign it, their signature will show that you have provided the study with your verbal assent to participate. [Allow child to ask questions]

\_\_\_\_\_, now that all of your questions have been answered and you have had time to think about the study, would you like to participate in Project I-PAL?

---

Printed Name of Volunteer

---

Age

Verbal Assent Obtained

Verbal Assent Declined

---

Signature of Staff Member Administering Informed Consent

---

Date