Duke University Health System

Consent to Participate in a Research Study
MINOR

Parks & Pediatrics Fit Together: Translating knowledge into action for child obesity treatment in partnership with Parks and Recreation (Pro00106453)
Bull City Fit Cohort

KEY INFORMATION SUMMARY

The purpose of this study is to evaluate a community-based wellness program and understand if it helps children and families be healthier. You and your child are being asked to take part in this research study because your child is a patient at Healthy Lifestyles and was referred to Bull City Fit, and is 5 to 12 years old.

All participating caregivers will be asked to complete surveys about their demographics and feedback about the program. We will also collect information from your child's medical record. Participating children may be asked to wear a fitness tracker during a few Bull City Fit sessions. The duration of participation is approximately 6 months.

There are minimal risks to participating. Some questions we ask you in the survey are personal and may make you feel uncomfortable. There is a risk of inadvertent disclosure of private health information. You will be compensated for participating. Participation is voluntary, and you can decline to participate or withdraw at any time. Your child may still attend Bull City Fit even if you decline to participate or your child declines to wear the fitness tracker.

If you are interested in learning more about this study, please continue reading below.

Research studies are voluntary. You do not have to agree to be in this study or allow your child to be in this study. Please read this consent form carefully and take your time making your decision. The study team will discuss the study with you. Please ask about any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to participate or allow your child to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below and will be reviewed with you and your child by the study team.

Please tell the study doctor or study staff if your child is taking part in another research study.

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Dr. Asheley Skinner, PhD, will conduct the study. The study is funded by a grant from the National Institutes of Health (NIH). Portions of Dr. Skinner and their research team's salaries will be paid by this grant.

Who will be my child's doctor on this study?
If you decide to have your child participate, your child's usual doctor will continue to be their doctor for the study. Our study team will contact your child's doctor during their participation in the study if needed.

Why is this study being done?
The purpose of this study is to evaluate a community-based wellness program and understand if it helps children and families be healthier. We will be looking at changes in your child's body mass index (BMI), physical activity and fitness, and participation in the program over time. We hope to better understand the impact of the program on children with high BMI who are making lifestyle changes.

Up to 75 children (and their caregiver) will take part in this study at Duke and about 150 people will take part in total from all the participating sites.

What is involved in the study?
If you agree to be in this study, you will be asked to sign and date this consent form to consent for your own participation and to consent for your child's participation.

For all study participants, we will record information in a secure database accessible only to approved members of the study team. Data collected by our team includes:

- Your child's medical record data (height, weight, BMI, blood pressure, labs, diagnosis of chronic medical conditions, and medication use)
    - We will collect this information from any regular clinical appointments that your child attends at Healthy Lifestyles or Duke University Health System clinics from the time your child was first referred to Healthy Lifestyles through the end of participation in the study. Clinical recommendations for pediatric weight management recommend follow up visits every 3 months with your child's doctor.

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    - We also will collect your child's annual height, weight, and visit date until age 18
- Surveys completed by caregiver at the time of enrollment in the study, 3 months, and 6 months. Surveys are related to demographics, program satisfaction, program assessment of harms and feedback, and adverse events.
- Bull City Fit attendance data from the first time you started attending Bull City Fit, throughout the duration of the study
- Your child's activity data from Bull City Fit sessions (explained below).

At select Bull City Fit sessions, we may also ask your child to wear an Accelerometer during the session to allow us to measure fitness and activity data. Your child may decline to wear it or can remove it if they choose. The accelerometer will be worn on your child's wrist like a watch. Accelerometers are devices that measure your physical activity, sleep, and outdoor exposure. The accelerometer used in this study (Axivity AX3) does not include GPS monitoring. It tracks movement and physical activity, but does not track your location. We would collect it at the end of the session before you leave.

Our team may reach out to you by phone, text, email, MyChart, or mailed letter throughout the study to help us collect this information. We may also contact you after completion of the program to ask about your experience in the program.

The database with this information will be held at Duke University and in the care of Dr. Asheley Skinner, PhD from Duke University.

Will I be given research results that may affect my child's medical care?
We do not expect to have any individual clinically relevant results of this research.

How long will my child be in this study?
You and your child will participate in this study for approximately 6 months. You can stop your own participation or your child's participation at any time without penalty. However, if you decide to stop your child's participation in the study, we encourage you to talk to your child's doctor first.

What are the risks of the study?

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There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your and your child's information confidential; however, this cannot be guaranteed. Some of the questions we will ask you/your child as part of this study may make you/them feel uncomfortable. You/Your child may refuse to answer any of the questions and you/your child may take a break at any time during the study. You may stop your child's participation in this study at any time.

Our research assistants and program coordinators may email or text you to discuss study related information or schedule a time for us to call you to complete surveys. We may use Google Voice for text messages and calls. Google Voice is a web-based, third-party service. Duke does not have a contract with Google to keep your information confidential, and the study team does not have full control over internet security, Google privacy policies, or phone carrier privacy policies. Text messages will be sent using SMS. The SMS text messages and emails are unencrypted and may be intercepted or visible to be read by third parties and there is no assurance of confidentiality of information communicated by an unencrypted text message. However, we will make every effort to keep your information confidential.

Are there benefits to taking part in the study?
We don't expect any health related benefits as a result of participating in the study. We hope that in the future the information learned from this study will benefit other people with your child's condition.

Will my child's information be kept confidential?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you and your child is kept confidential, but we cannot guarantee total confidentiality. You and your child's personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. You and your child's personal information may also be given out if required by law.

As part of the study, results of any study-related tests or procedures may be shared with NIH and its affiliates. In addition, your child's records may be reviewed in order to meet federal or state regulations. Reviewers may include:

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- representatives and affiliates of NIH
- the Duke University Health System Institutional Review Board,
- others as appropriate.

If any of these groups review your child's research record, they may also need to review your child's entire medical record.

All of the surveys and wearing the accelerometer are being done only because your child is in this study. The study results will not be provided to you OR sent to your child's personal healthcare provider.

The study results will be retained in your child's research record for six years after the study is completed or until your child reaches the age of 21 years, whichever is longer. At that time, either the research information not already in your child's medical record will be destroyed or information identifying your child will be removed from such study results at DUHS. Any research information in your child's medical record will be kept indefinitely

This information may be further disclosed by the sponsor of this study or to outside reviewers for audit purposes. If disclosed by the sponsor or outside reviewers, the information is no longer covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your child's name or other personal information will not be revealed.

Some people or groups who receive your child's health information might not have to follow the same privacy rules. Once your child's information is shared outside of DUHS, we cannot guarantee that it will remain confidential. If you decide to share your child's information with anyone not involved in the study, the federal law designed to protect your child's health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

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The National Institutes of Health (NIH) has issued a Certificate of Confidentiality (CoC) for this study. This means that the researchers cannot release or use information, documents, or samples that may identify your child in any action or lawsuit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings, like a court order.

There are some important things that you need to know about the CoC:

It DOES NOT stop reporting required by federal, state or local laws. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats your child will harm themselves or others.

It CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs, including when the Food and Drug Administration (FDA) requires it.

It DOES NOT prevent your child's information from being used for other research if allowed by federal law.

Researchers may release information about your child when you say it is okay. For example, you may give them permission to release your child's information to insurers, medical providers or any other people not connected with the study. The CoC does not stop you from willingly releasing information about your child's involvement in this study. It also does not prevent you from having access to your child's information.

Will it cost me anything for my child to be in the study?
There are no additional costs to you for you and your child's participation in this study. You and your child's insurance company will not be billed for your child's participation.

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Will I be paid for my child to be in the study?
You will receive up to $60 for your expenses related to your child's participation (parking, gas, and time). You will receive $20 for completing surveys when you and your child enroll, $20 for completing surveys at the 3-month timepoint, and $20 for completing surveys at the 6-month timepoint. You will be paid by electronic giftcard.

You will only be paid for the visits your child completes. In order to issue your payment, Duke University may need to collect your name and email address or phone number. If you do not want to provide this information, you cannot be paid but you can still allow your child to take part in the research study.

What about research related injuries?
Immediate necessary medical care is available at Duke University Medical Center in the event that your child is injured as a result of their participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to your child in the event of a study-related injury.

For questions about the study or research-related injury, contact Asheley Skinner at 919-681-6801 during regular business hours, after hours and on weekends and holidays.

What if I want to withdraw my child from the study?
If you agree to allow yourself and your child to be in the study, you may withdraw yourself and your child from the study at any time. If you withdraw from the study, no new data about you or your child will be collected for study purposes other than data needed to keep track of your and your child's withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to allow yourself/your child to participate or to withdraw yourself/your child from the study will not involve any penalty or loss of benefits to which you and your child are entitled, and will not affect you or your child's access to health care at Duke. If you do decide to withdraw your child, we ask that you contact Dr. Skinner in writing and let them know that you are withdrawing your

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child from the study. Their address is 215 Morris Street, Suite 210, Durham, NC 27701.

We will tell you and your child about new information that may affect your child's health, welfare, or willingness to stay in this study.

Your child's data may be stored and shared for future research without additional informed consent if identifiable private information, such as your child's name and medical record number, are removed. If your child's identifying information is removed from their samples or data, we will no longer be able to identify and destroy them.

The use of your child's data and samples may result in commercial profit. You will not be compensated for the use of your child's data and samples other than what is described in this consent form.

A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by U.S. Law. This Web site will not include information that can identify your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Whom should I call if I have questions or problems?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Skinner at 919-681-6801 during regular business hours, after hours and on weekends and holidays. You can also contact the lead study coordinator, Janna Howard, at 919-794-7576 or fittogether@duke.edu.

You can call the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111 if:

- You have questions about your child's rights as a research participant
- You wish to discuss problems related to the research
- You have any concerns or suggestions related to the research
- Want to obtain information or offer input about the research

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree for myself and my child to be in this study, with the understanding that I may withdraw myself and my child at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____N/A – waiver of consent for children (age 5-12)

_____	_____	_____
Signature of Subject (if 12 years or older)	Date	Time
_____	_____	_____
Signature of Participating Parent/Guardian	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time