Children's Hospital of Philadelphia

Informed Consent and HIPAA Authorization Form

Study Title: A Low-Cost, Collaborative Tool for the Tracking of Youth Activities to Reduce Risk of Physical Injury

Version Date: 3/19/2021

Consent Name: Phase 1 Consent Form

Principal Investigator: J. Todd R. Lawrence MD PhD Telephone: (215) 590 1527

Study Overview

You or your child are being asked to take part in this research study because you are a youth baseball pitcher between the ages of 8 and 14 years old. The purpose of this study is to obtain information to help us develop a small wearable device that collects and tracks information (such as force) about throwing movements during youth athletic activity to identify and track arm fatigue.

This device is not approved by the FDA.If you agree to take part, your participation will include a single visit that will last about three hours. As a participant in this research, you will be asked to perform various baseball-related movements, including a simulated baseball game, at the Epics Sports Biomechanics research facility. During some of the session, you will be asked to wear a small, over-arm throwing device. You will also be asked to do these baseball-related movements while being recorded with movement sensors at the Epic Sports Biomechanics research facility.

The main risks of this study include a small risk of loss of data confidentiality and a minor risk of skin discomfort from wearing the device. There is also a minor risk that you could become injured as a result of the additional athleteic activity which you will be asked to participate in. Any additional activity, however, will not be beyond the strain of normal practice or athletic competitions.

You will not benefit from your participation in this study. Knowledge gained from this study will help investigators build devices that could help reduce youth athletic injuries in the future. Participation in this study is voluntary. If you do not choose to take part in this study, it will not affect your care.

If you are interested in learning more about the study, please continue to read below.

In the sections that follow, the word "we" means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child.

How many people will take part?

About 40 children will take part in this study. 20 subjects will participate in Phase 1 of the study, which you are being asked to enroll in, and 20 subjects have participated in an earlier Pilot Phase.

What are the study procedures?

Some of the procedures in this study will be repeated several times. Procedures that are part of your regular, routine medical care will continue to be performed as this study is separate from your medical care. The study involves the following procedures. The entire study visit will take approximately three hours to complete.

Study Device: You will need to wear the study device when asked to during the study session. The device is a small motion sensor that will be held in a small plastic box, which will then be placed in a fabric sleeve. A photo of the device is pictured below on a leg. You will be asked to wear a similar sleeve containing the device on your arm.

Physical Exam: You will be asked to undergo a physical exam which will include height, weight, and range of motion measurements.

Video Recording: You will be video-recorded while performing some of the study activities.

Activities: You will be asked to participate in a simulated baseball game (approximately 30-45 pitches) while wearing the throwing device.

In addition, you will be asked to perform a set of other baseball-specific movements such as field-based overhand throws, runs, bat swings, and ball-catching. Each of these actions will be performed approximately 10 times in random order. Approximately 50 small sensors will be placed on you, which will

track your movements during the session. Movement data will be recorded with motion analysis cameras at different perspectives while your perform these movements.

Questionnaires: You may be asked to fill out questionnaires regarding your demographic information and your athletic history. This will take approximately ten minutes to complete. If you are found to be ineligible for the study after questionnaire completion, you will not be able to complete the study.

Visit Schedule

There will only be one study visit for this study You will not be asked to come in for any additional visits.

What will be done with my data?

During the study, we will collect data from the wearable throwing device. The device will count number of throws and measure movements. Data collected from this device and from the motion monitoring systems at the Epic Sports Biomechanics will be stored securely on the Orthopaedics research drive. Data collected in this study will be sent securely to our research partners at Innovative Design Labs at the University of Pennsylvania. Data transferred to Innovative Design Labs may contain identifiable information and video footage from the motion analysis.

Will I receive any results from the tests done as part of this study?

You will not receive any results from this study.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. The risks of taking part in this study are discussed below.

Risks associated with the study device:

There is a potential risk of skin irritation from wearing the study device. Because the device is investigational, there may be risks that we do not yet know about.

Risks from other study procedures:

There is a chance that the physical examination and some of the questions asked in the questionnaires might make you feel uncomfortable. You do not have to answer any questions or complete any other study procedures that you don't want to. There is also a small risk from a loss of confidentiality. We will do our best to reduce this risk by keeping your information in a password protected computer in the locked reseach office and by securely transferring and storing any of your data that is transferred to Innovative Design Labs.

There is also a minimal risk that you may become injured while being asked to perform different throws and movements typical of youth baseball play. However, this risk will be minimized because you will be under the supervision of a trained physical therapist and you will be able to discontinue any throw or movement that makes you uncomfortable.

Are there any benefits to taking part in this study?

There are no direct benefits to participating in this study. The knowledge gained from this research may help doctors determine more effective ways to prevent shoulder and arm injuries in youth athletics.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. You have the option to download a pdf of this form by using the buttons provided on this form. The option to print a signed copy of the form will appear after completing the form.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason. There are no consequences for withdrawing from this study.

What choices do you have other than this study?

The only alternative to participating in this study is not participating.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. This will include information from the throwing analysis, a physical exam, and demographic and athletic history surveys. This could include physical exams or tests done in the clinical lab. Staff will view your research records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP, the University of Pennsylvania, and Epic Sports Biomechanics
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.
- The National Institutes of Health who is sponsoring this research;
- The US Food and Drug Adminstration, who is regulating this research;
- Your data will be shared with outside collaborators including Innovative Design Labs, who will analyze and securely store your data, including some identifiable data such as video footage from the motion analysis.

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your identifiable information.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable informationfor a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your data could be shared for:

- other scientific research;
- product development at Innovative Design Labs

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The National Institute of Health may need information to assess this project.
- The US Food and Drug Administration (FDA) may need information.

- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. J. Todd R. Lawrence
The Children's Hospital of Philadelphia
Division of Orthopaedics
34th Street and Civic Center Blvd.
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Financial Information

This study is separate from your medical care and will incur no additional cost.

Will there be any additional costs?

There will be no additional costs to you by taking part in this study. The Epic Sports Biomechanics analysis will be provided free of charge to you. This study is separate from your medical care and will not affect the cost of your medical care.

Will you be paid for taking part in this study?

You will receive a $50 giftcard to compensate you for your time, effort, and inconvenience.

If you receive payment using a bankcard, the bank will have access to some personal information in order to process your payment. The bank will not have access to any medical information.

We may share your data with third parties (other researchers/institutions or for profit companies). Your data may be used for commercial profit. You will not receive any financial benefit from the use of your data.

Who is funding this research study?

The National Institutes of Health is providing funding for this study. The Division of Orthopaedics at The Children's Hospital of Philadelphia is also providing some funding for this research.

Please ask Dr. Lawrence if you have any questions about how this study is funded.

Conflicts of Interest

Two of the study doctors, Dr. Lawrence and Dr. Greenberg, have significant financial interest in the throwing monitor device, which is being evaluated in this study. If the study shows that the device may be useful for preventing injury in youth athletics, Dr. Lawrence and Dr. Greenberg may receive income from this invention.Innovative Design Labs and CHOP has a significant financial interest in the study device being evaluated in this research study. In the event that the study device proves to be effective, Innovative Design Labs and/or CHOP may receive significant financial benefit.

What if you have questions about the study?

If you have questions about this study or how your samples/data are going to be used, call the study doctor, Dr. J. Todd Lawrence (215-590-1527).You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

What will be done with my data when this study is over?

We will use and may share data for future research. They may be shared with researchers/institutions outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your child's participation. You are also authorizing the use of your/your child's health information as discussed above. **NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

Name of Subject	
Name of Authorized Representative (if different than subject)	Relation to subject: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative	Date

Child Assent to Take Part in this Research Study

For children capable of providing assent:

I have explained this study and the procedures involved to _____ in terms he/she could understand and that he/she freely assented to take part in this study.

_____

Person Obtaining Assent

_____ _____

Signature of Person Obtaining Assent Date

This study has been explained to me and I agree to take part.

_____ _____

Signature of Subject (optional) Date