

RESEARCH PARTICIPANT CONSENT FORM

Prevention of Shoulder Injury in the Overhead Throwing Athlete

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Invitation to Take Part:

You are being invited to take part in the above entitled research project. As a male baseball player between the ages of 8 and 15 years old, you are eligible for this study. This research project has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston as HSC-GEN-08-0552.

Purpose of Research:

Shoulder injuries are very common in overhead throwing athletes, particularly baseball and softball players. They occur from repetitive throwing which alters the bones and ligaments of the shoulder. This research will compile measurements on youth throwers to determine if differences exist in those who throw a high number of balls per year and those who do not. For any of those throwers who are found to have stiffness of one particular ligament in the shoulder, an attempt will be made to determine improvements in that stiffness by comparing measurements taken before and after a customized stretching and exercise program. It is believed that the stiffness leads to injuries, and thus improvements in the stiffness will reduce injuries, which require surgery, or end players' careers.

The hypothesis of this study is that stiffness of that ligament can be correlated to the amount a player throws, and also that this stiffness can be improved by the stretching and exercise program. It is further anticipated that we can show that this stretching reduces the chance of injuries requiring surgery or cessation of throwing sports.

Specific Procedures to be used:

1. Players will typically be youth throwers, and as such will have their parents or legal guardians review and sign this document for informed consent.
2. A 1-page thrower's history form will be completed.
3. Each player will have both shoulders measured for range of movement while lying flat on their back.
4. Measurements will be entered into a spreadsheet that will give a numerical estimate of how tight the athlete's posterior inferior glenohumeral ligament may be.
5. If the measurements reveal that there may be tightness, the athlete will be given a sheet detailing stretching exercises.
6. The player will have repeated measurements at monthly intervals until the ligament is no longer tight.
7. This will be repeated yearly and the rate of injuries that occur will be recorded. It is anticipated that there will be no shoulder injuries in the players without tight ligaments, and also no shoulder injuries in the players who start out with tight ligaments but who complete their stretching exercises.

Duration of Participation:

The first measurements are obtained at screening examinations, which take approximately 5 minutes, and can be reduced to 1 minute if this consent form and the 1-page thrower's history form are filled out ahead of time by downloading from the website at www.SafeThrow.com under the Screening Section. There is often a short line at screening exams since they are done by team or in a similar group setting, and thus the total time commitment can be 10-20 minutes.

Any player who is found to have ligament tightness will be so informed at the time of this short screening examination. A single sheet of stretching exercises will be provided, and these take about ten minutes three to four times per week. Those players will be asked to schedule a follow-up measurement about one month later.

Risks to the Individual:

This study poses minimal risks to the players, and the risks are no more than the participant would encounter in everyday life.

Benefits to the Individual or Others:

There is benefit to participants in this study in that a screening for potentially harmful ligament tightness in the shoulder is provided. If such tightness is identified, the player will be given exercises that can improve the long-term function of the throwing shoulder. General arm conditioning exercises are provided at the time of screening as well for the players' benefit.

Extra Costs to Participate:

There shall be no cost to the player or family to participate in this study, other than transportation costs to and from the screening examinations.

Confidentiality:

No data collected during the study will ever be released to any party excepting requests from periodical editors during the publication process. No patient identifiers such as name or email will ever be released, even to publishers or editors, or to any other person or institution. Records will be maintained on only one computer, at the place of business of the principal investigator. Backup data will be maintained at that location and the investigator's home. Data will be retained for approximately nine years, as the duration of this study is estimated to be five to seven years, and data should be stored for two years after the completion of the study.

Voluntary Nature of Participation

I do not have to participate in this research project. If I agree to participate I can withdraw my participation at any time without penalty. A decision not to take part, or to stop being a part of the research project will not change the services that are available to you from Dr. Metzger.

In Case of Injury:

If you suffer any injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, all needed facilities, emergency treatment and professional services will be available to you, just as they are to the community in general. You should report any injury to Dr. Metzger (Charles Metzger, M.D., phone (713) 333-9333) and to the Committee for the Protection of Human Subjects at (713) 500-7942. You will not give up any of your legal rights by signing this consent form.

Contact Information:

If I have any questions about this research project, I can contact Dr. Charles Metzger at (713) 333-9333, or email cmetzger@houstonortho.com

I HAVE HAD THE OPPORTUNITY TO READ THIS CONSENT FORM, ASK QUESTIONS ABOUT THE RESEARCH PROJECT AND WILL PARTICIPATE IN THIS PROJECT.

Participant's Signature

Date

Participant's Name

Parent or Guardian Signature

Date