

**University of Wisconsin-Madison  
Assent and Consent to Participate in Research  
and  
Authorization to Use Protected Health Information for Research**

**Study Title for Participants:** Injury risk factors in female high school volleyball players  
**Formal Study Title:** Identifying risk factors for injuries in female high school volleyball players  
**Lead Researcher:** Tim McGuine, Ph.D.  
**Where Lead Researcher works:** Department of Orthopedics and Rehabilitation

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**Invitation**

We invite you to volunteer to be a part of a research study about risk factors for injury in high school volleyball players. We are inviting you because you are in high school and play volleyball on your school's team.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study, and requests your authorization (permission) to use your health information. If you want to talk to your family and friends before making your decision, you can. Once we have answered all your questions, you can decide if you want to be in the study. This process is called "informed consent." You can choose not to take part and if you join, you may quit at any time. Ask questions about anything in this form that is not clear. All of your questions should be answered to your satisfaction before you sign this form.

**Why are researchers doing this study?**

The purpose of this research study is to find out which factors might change how much at risk a volleyball player is for getting injured, and find out how these factors might change over the course of the volleyball season. We are doing this research because volleyball is a very popular high school sport. Players are encouraged more now than in the past to specialize in volleyball and to play year-round. We know from other studies that specializing in one sport can increase the chance of an injury. We would like to know whether that happens with volleyball players, and what other factors might influence the injury rate.

This study is being done at the University of Wisconsin-Madison (UW-Madison). A total of about 1300 people will participate in this study. Funding for this study is provided by the National Federation of High School Associations and the University of Wisconsin, Dept. of Orthopedics - Sports Medicine Program.

**How long will I be in this study?**

You will be part of the study for about 3 months, during your high school volleyball season. The researchers may take you out of the study, even if you want to continue, if:

- you do not follow the study rules or no longer meet the requirements to be in the study, or
- the study is stopped by the researchers

**What will happen in this study?**

If you decide to participate in this research study, the researchers will ask you to fill out some questionnaires at three times during the season: at the very beginning, in the middle of the

season, and when the season has ended. The questionnaire asks questions about injuries you have had, if you have used over the counter pain medications, how much you sleep and how you feel. Your school's athletic trainer will also do a quick test of your joint laxity – how loose your joints are – on the first survey day. This test asks you to bend a few places on your body, and takes just a few minutes.

You may skip any question on the questionnaires that you do not wish to answer.

### **How we will use your protected health information (PHI)**

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Results of tests or procedures done as part of the study
- Things you tell your athletic trainer or the researchers about your health

### **Do I have to be in the study? What if I say “yes” now and change my mind later?**

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study. Let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect your volleyball team participation. No matter what decision you make, and even if your decision changes, there will be no penalty to you. This is also true about any treatment relationship you have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) will last until the research study is done. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the lead researcher, Tim McGuine, at 621 Science Dr., Madison, WI 53711.

### **Will being in this study help me in any way?**

Being in this study will not help you directly. But your participation in the study may benefit others in the future by helping us learn more about what factors increase or reduce the chances of high school volleyball players getting injured.

### **What are the risks?**

There are no additional risks to joining this study compared to those who do not participate. Anytime information is collected, there is a small risk that your information could become known to someone not involved in this study. However, the information we collect from you will be kept private to the best of our ability.

**Will being in this study cost me anything?**

There will be no cost to you for any of the study activities or procedures.

**Will I be paid or receive anything for being in this study?**

We will not pay you to take part in this study or pay for any out of pocket expenses related to your participation, such as travel costs.

**What happens if I am injured or get sick because of this study?**

Being injured during this research is very unlikely. However, accidents can happen. If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, talk to your athletic trainer or your regular health care provider.
- Let your athletic trainer know so he or she can let the researchers know about your sickness or injury.

Here are some things you need to know if you get sick or are injured because of this research:

- If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
- Your health insurance company may or may not pay for this care.
- No other compensation (such as lost wages or damages) is usually available.
- UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
- By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

**How will the researchers keep my research information confidential?**

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your health information, your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study.

**Who at UW-Madison can use my information?**

- Members of the research team

- Offices and committees responsible for the oversight of research

**Who outside the UW-Madison may receive my information?**

Nobody outside the UW-Madison is allowed to receive your information.

**Will information from this study go in my medical record?**

None of the information we collect for this study will be put in your medical record.

Authorizing the research team to use your PHI means that we can release it only to the people or groups listed above, and only for the purposes described in this form.

Also, if ALL information that can identify you is removed from the health information collected in this study, then it is no longer PHI and this authorization will no longer limit how the remaining information can be used. This means the information could be used or shared for other reasons, such as a research study about another question. It also means that the information could be shared with researchers working at institutions that are not listed above.

**What if I have questions?**

If you have questions about this research, please contact the Lead Researcher, Tim McGuine, at 608-265-6516. If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

**Agreement to participate in the research study**

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
  - You have had a chance to ask questions about the research study, and the researchers have answered your questions.
  - You want to be in this study.
  - You give authorization for your protected health information to be used and shared as described in this form.
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Printed Name of Participant

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Signature of Research Participant

Date

If you are the parent or legal guardian of a minor who is invited to take part in this study, your child can participate in the study only if you give your permission.

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Printed Name of Parent

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Signature of Parent

Date

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Name of the Person Obtaining Consent and Authorization

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Signature of Person Obtaining Consent and Authorization

Date

**\*\*You will receive a copy of this form\*\***