The UNIVERSITY OF CHICAGO
The Division of the Biological Sciences • The University of Chicago Medical Center

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: IRB21-0678 Name of Subject: _____

Medical History Number: _____

STUDY TITLE: **The Diagnostic Accuracy of Pocket Size Ultrasound (PsUS) in the Detection of Pediatric Elbow Fractures**

Doctors Directing Research: Holly Benjamin MD and Alisa Brennan MD
Address:
5841 S. Maryland Ave, M/C 0810
Chicago, IL 60637-1443
Telephone Number: 773-702-6760

KEY INFORMATION

You are being asked to participate in a research study involving a pocket-sized ultrasound device. A member of the research team will explain what is involved in this study and how it will affect you. This consent form will describe the study procedures, the risks, and the benefits of participation, as well as how your confidentiality will be maintained during the duration of the study. Please take your time to ask the research team questions. This process is called informed consent and feel comfortable making a decision whether to allow your child to participate or not. If you decide to participate in this study, you will be asked to sign this consent form. If you have questions later, the contact information for the research investigator in charge of the study is above. Throughout this consent form, "you" will refer to either "you" the subject or your child.

WHAT IS THE STUDY ABOUT?

The purpose of this study is to take ultrasound images of your injured elbow to see if this new machine can see signs of injury. We will take these ultrasound images using a new type of ultrasound that is very small and can fit in a person's pocket. By doing this study, we want to learn if this pocket-sized ultrasound device can take clear enough pictures to reliably show a broken or injured elbow in children.

HOW LONG WILL IT LAST?

Your active participation in this research will last about 10 minutes and involve a short ultrasound exam using the pocket-sized device. After the ultrasound exam, you will continue to receive your standard clinical care from the emergency room team. You will also receive a follow up call in 1 month after your initial ED visit to check in regarding your elbow injury. We will keep your information for 5 years.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

There will not be any direct medical benefit to you. However, we hope that your participation in

the study may benefit other individuals in the future by helping us learn more about the usefulness of pocket-sized ultrasound devices in the evaluation of acute elbow fractures in children. Participation in the study will not interfere with your routine clinical care. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

The risks of this study and an ultrasound exam are minimal. The gel that is used to obtain the pictures is sometimes cold and you may feel pressure or pain on your elbow while we obtain the images. For a complete description of risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

Taking part in this study is voluntary. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

You may choose not to participate at any time during the study. You will not lose any services, benefits or rights you would normally have if you choose to leave the study. The University of Chicago/University of Chicago Medical Center will not condition (withhold or refuse) treating you on whether you sign this Authorization or revoke your authorization at a later time. If you do not sign this form, you will not receive the research-related intervention(s).

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Holly Benjamin of the University of Chicago. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information above.

For questions about your rights as a research subject, please contact the University of Chicago BSD IRB at 773-702-6505.

DETAILED CONSENT

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 70 children will take part in this study at the University of Chicago Medicine Comer Children's Hospital.

WHAT IS INVOLVED IN THE STUDY?

If you agree to participate in this study, you will first be asked to sign this consent form.

If you are agree to participate in this study, we will use a small pocket-sized ultrasound device to take pictures of your elbow for signs of injury. The total time to take these pictures will be 5-10 minutes. During this study, we will also collect information about you including: your age, gender, medical record number, data of exam, presenting emergency room complaint, physical exam, radiographic elbow images, and radiology reports of images (if applicable).

This ultrasound is being done for research purposes only. The ultrasound is not performed for any diagnostic reasons. This information will not be available to you. If any ultrasound findings are concerning, we will discuss findings with your primary ED care team. If this occurs, your medical care team may ask you to have additional imaging done as part of your standard clinical care.

During this study, Dr. Holly Benjamin and her research team will collect the following data from your medical chart: age, gender, medical record number, data of exam, presenting emergency room complaint, physical exam, radiographic elbow images, and radiology reports of images. This will not interfere with the timing of the diagnostic or therapeutic interventions, or recovery time.

In future, identifiers associated with your data could be removed from the data. The de-identified data could then be used for future research by our research team or other researchers without notifying you or asking your permission for this use.

The results from this study will not be shared with you.

Dr. Benjamin may decide to take you off of the study without your consent if:

- You are unable to meet the requirements of the study or your medical condition changes;
- New information becomes available that indicates that participation in this study is not in your best interest; or
- If the study is stopped.

WHAT ARE THE RISKS OF THE STUDY?

The risks of ultrasound exam are minimal. The gel that is used to obtain the pictures is sometimes cold and you may feel pressure or pain on your elbow while we obtain the images.

The main risk of this study is loss of confidentiality. Please see the "What about Confidentiality?" section below for more information.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there will not be any direct medical benefit to you. We hope that your participation in the study may benefit other individuals in the future by helping us learn more about the usefulness of pocket-sized ultrasound devices in the evaluation of acute elbow fractures in children.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you may choose not to participate.

WHAT ARE THE COSTS?

Clinical services provided during a clinical research study are either research-related or considered part of usual medical care for patients with your disease or condition. Tests, procedures, and activities that are ordered by your medical care team to monitor your disease or condition (whether you are participating in a clinical trial or not) are described as 'usual medical care'. 'Research-related' is the term used to describe any tests, procedures, or activities that you are being asked to undergo only because of your participation in this clinical research study.

You or your insurance will be financially responsible for the costs of your usual, ongoing medical care. This often includes regular visits with your doctor, lab tests, and other tests and procedures deemed medically necessary by your care team. Financial responsibilities for routine care may include deductibles and co-payments and this care will be subject to all the same requirements and restrictions of your insurance.

You will not be responsible for the costs of tests or services that are being performed solely for the purposes of this study and would not be performed if you were not participating in this clinical research study. This may include additional tests to answer a research question that are not required for your routine clinical care.

If you have questions about whether specific clinical services are research related or part of your usual medical care, please speak to your physician or research contact person.

WHAT HAPPENS IF I HAVE AN INJURY?

If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, the University of Chicago Medical Center will provide such treatment at the University of Chicago Medical Center at no cost to you. Costs of related non-emergency care for an unanticipated research injury will be covered if that care is provided at the University of Chicago Medical Center. You must notify Dr. Holly Benjamin as promptly as possible after your injury in order to receive this care. An injury is "unanticipated" if it is not one of the known effects of a study drug, medical device or procedure. If you think that you have suffered a research related injury, you must let Dr. Benjamin know right away.

WILL I BE PAID FOR MY PARTICIPATION?

You will not be paid to participate in this study.

WHAT ABOUT CONFIDENTIALITY?

There is a risk of potential loss of confidentiality. To minimize this risk, study records that identify you will be kept confidential. Your medical data will be stored on a secure, password-protected,

encrypted, HIPAA-compliant, web-based imaging database and data collecting system. Additional physical data will be stored in a secure locked cabinet in the pediatric emergency room fellows office. The only individuals with access to this data would be Dr. Holly Benjamin as well as her research team. The images will only include an assigned study number and will not contain your name, date of birth, or medical record number.

During this study, Dr. Benjamin and her research team will collect protected health information (PHI) about you for the purposes of this research. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago. Protected Health Information (PHI) consists of any health information that is collected about you, which could include your medical history and new information collected as a result of this study. All of this information will come from your medical record. The information to be used on this study includes age, gender, medical record number, data of exam, presenting emergency room complaint, physical exam, radiographic elbow images, and radiology reports of images (If applicable). Once enrolled, you will be given a unique code so that the names and medical record numbers will not be disclosed.

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including the Office of Human Research Protections (OHRP). Representatives of the University of Chicago, including the Institutional Review Board (a committee that oversees the research) and the Office of Clinical Research may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

During your participation in this study, you will have access to your medical record. Dr. Benjamin is not required to release to you research information that is not part of your medical record.

This consent form will be kept by the research team for 5 years. The study results will be kept in your research record and be used by the research team for 5 years.

At the time of study completion, either the research information not already in your medical record will be destroyed or information identifying you will be removed from study results.

Data from this study may be used in medical publications or presentations. Your name and any other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time. We will also retain de-identified ultrasound images indefinitely for educational purposes.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Drs. Holly Benjamin or Alisa Brennan in writing at the address on the first page. Drs. Holly Benjamin or Alisa Brennan may still use your information that was collected prior to your written notice.

You will be given a signed copy of this document. Your authorization to use and disclose your

health information does not have an expiration date.

CONSENT

SUBJECT ASSENT (FOR 12-16 YEAR OLDS)

The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

I agree to participate in this study. My participation is voluntary and I do not have to sign this form if I do not want to be part of this research study.

Signature of Subject: _____
Date: _____
Time: _____AM/PM (Circle)

PERSON OBTAINING CONSENT

I have explained to _____ **[insert name of subject/parent/guardian when obtaining consent]** the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject and family.

Signature of Person Obtaining Consent: _____

Date: _____

Time: _____AM/PM (Circle)

PARENT/GUARDIAN:

I give my permission for my child/relative/the person I represent to participate in the above described research project.

Signature of Parent/Guardian: _____

Date: _____

Time: _____AM/PM (Circle)

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