UNIVERSITY OF CALIFORNIA IRVINE
MINOR ASSENT / PARENTAL PERMISSION / ADULT CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT TO BE IN A STUDY

Echocardiogram Screening of Young Athletes for Cardiac Abnormalities in a Community Setting

RESEARCH TEAM
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In the instance of parental permission, "you" means "your child."

What is the study about?

The doctors and researchers are asking you to take part in a research study about whether having an ultrasound test before participating in sports at school will find any hidden problems with your heart.

Why are they doing this study?

They want to find out if there are any hidden problems with your heart that could begin to cause problems once you start playing sports.

What will happen to me?

You will be asked to fill out a form about you and your family's medical history. The doctors are performing an echocardiogram as part of the screening. Echocardiogram means that they will place some gel on your chest and then put a small sensor called a probe on top of the gel to get a virtual image of your heart.

The doctors will write down the results of the procedure. Doctors may store the virtual images of your heart in a secure electronic database. If they see anything unusual, they will recommend that you see your usual doctor for a checkup.

Is it harmful for me to be in this study?

No, it is not dangerous to be in this study. The ultrasound test is painless and will only take a few minutes. The research part involves gathering data about your test.

What if I have any questions?

I can ask questions any time. I can talk to the doctors or I can talk to my parent(s). The phone number I can call is 949-842-2167.

Do I have to be in the study?

I do not have to be in the study if I do not want to be. I can say "Yes" now and change my mind later. Also, I understand that I can talk this over with my parent(s)/guardian(s). My mom or dad will also be asked to give their permission for me to take part in this study. But even if my parent(s) say "Yes" I can still decide not to participate in this study and say "No."

Purpose of study:

Young people with cardiac abnormalities such as Hypertrophic Cardiomyopathy (HCM) will often show no symptoms and are therefore often undiagnosed. The exertion on the heart caused by exercising can lead to sudden cardiac death in these athletes. Previous studies have shown that routine screening can lead to detection of some of these abnormalities and intervention or withdrawal from sport can reduce mortality. The purpose of this study is to screen for and determine the prevalence of abnormalities of the heart in a population of young athletes using echocardiogram (echo, which is an ultrasound of the heart) as well as perform a cost-effectiveness analysis of the screening. Subjects will be screened by trained echo technicians on their campuses and their results will be interpreted by board-certified pediatric cardiologists.

Subjects:

To be eligible for this study, you must be an athlete of high school or college age and be participating in your school athletics pre-participation physical examination.

Procedures:

If you elect to participate in the study, the time commitment will be approximately 5-10 minutes. We will collect data from you about your medical and family medical history on the health history form, and we will retain the form. This will not be added to your medical record.

An echocardiogram will be performed on you as part of the screening. The interpretation by a cardiologist of your echo as performed is part of the screening.

The research activity in this protocol will be the echo procedure, data collection of demographics, and echo results. If you have abnormal echo results, we will contact you by phone or mail recommending that you see your primary care physician. We will ask you to sign a HIPAA (Health Insurance Portability and Accountability Act) form giving permission for us to access your medical record for the purpose of following up on the results of the formal evaluation as well as the interventions taken such as medicinal, surgical, or withdrawal from exercise. All results of this study will be kept confidential from school personnel.

The investigator can remove me from the study without my consent for, but not limited to, the following reasons:

1. If it is judged to be in my best interest in an effort to protect my safety and welfare
2. If I experience an injury or illness that warrants ending my participation
3. If the study is stopped unexpectedly

Risks:

As this study involves the use of your identifiable information, the primary risk of the research is the potential breach of confidentiality. All efforts to ensure that this does not happen will be made including the following: once data is taken from the medical record and entered into a database, a special code will be assigned to my data set. This data will be locked in the office of the lead investigator who holds the only key. The link for the special code will be kept locked separate from the data set.

There is also a very minimal risk of mild skin irritation from the echocardiogram gel used.

There is risk of discomfort from disclosure of any abnormality.

There are no additional risks associated with my participation in this study.

Benefits:

The screening may potentially find an abnormality in your heart that was previously undetected. Your participation in the study may demonstrate that screening young athletes using echo can be cost effective and can reduce mortality if the appropriate interventions are taken.

Alternative Treatments:

If you choose not to participate in this study you will still receive the routine and standard pre-participation physical exam as required by your school.

Compensation and Costs

You will not be compensated for your participation in the study.

The screening is being provided free of charge and you will not be billed for your participation in the study.

If you seek further medical care following the screening, you will be responsible for all further costs.

Confidentiality:

Subject Identifiable Data and Data Storage

Dr. Fox will manage the study database and access to the database. There is a potential risk of breach of confidentiality. In order to minimize this risk, all identifiable information that will be collected about you will be removed and replaced with a study code. A list linking the study code and your identifiable information (decoding key) will be kept separate from the coded research data. This decoding key is the only way to link the data to the identifiers.

The repository will contain only coded data and will not contain any identifiable information. The decoding key will be locked in the office of Dr. Fox. Only study investigators will be given access to the study data and decoding key. All of the data collected will be stored in coded form, and will be kept in a locked computer in a locked cabinet in a locked facility at the UCI Medical Center Emergency Department that only the study investigators have access.

The data collected from this study may be made available to other researchers for further or separate studies.

Any information derived from this research project that personally identifies you will not be voluntarily released or disclosed without your separate consent, except as specifically required by law. Your identity will remain anonymous if the study results are published or presented. Stored imaging will only include the virtual ultrasound-generated images of your heart and will not contain any imaging of your leg, neck, or face.

Data Access

The research team, authorized UCI personnel, and regulatory entities such as the Office of Human Research Protections (OHRP) may have access to your study records to protect your safety and welfare. Any information derived from this research project that personally identifies you will not be voluntarily released or disclosed by these entities without your separate consent, except as specifically required by law. Research records provided to authorized, non-UCI entities will not contain identifiable information about you. Publications and/or presentations that result from this study will not include identifiable information about you.

Data Retention

The investigators intend to keep the research data for at least 6 years because the study involves Personal Health Information.

Financial Interests:

No one on the study team has a disclosable financial interest related to this research project.

New Findings:

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the researcher team listed at the top of the form.

If You Have A Question:

If you are unable to reach a member of the research team listed at the top of the form and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact UCI's Office of Research by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@rgs.uci.edu or in person at 141 Innovation Drive, Suite 250, Irvine, CA 92697-7600.

Voluntary Participation:

You should not sign this form unless you have read it and understand its contents. You may request a copy from school personnel or any research team member. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. The results of your screening will not be released to your school or athletics department. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center. Your signature below indicates that you have read the information in this consent form and have had a chance to ask any questions that you have about the study.

If you have any questions you can contact the research team at 949-842-2167.

PLEASE SIGN BELOW IF YOU AGREE TO PARTICIPATE IN THIS STUDY

_____	_____
School Name	Student Age

_____	_____	_____
Printed Student name **(Required)**	Student Signature **(Required)**	Date

_____	_____	_____
Printed Parent/Guardian name	Parent/Guardian Signature	Date

(**Required only if student under 18 years of age)**

_____	_____	_____
Printed Researcher name	Researcher Signature	Date

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@rgs.uci.edu; or by writing us at 141 Innovation Drive, Suite 250, Irvine, CA 92697