

Robert Wood Johnson University Hospital-Somerset
110 Rehill Avenue
Somerville, NJ 08876

Information and Consent for Research

Title of the Project: The Student Athlete Cardiac Evaluation Registry

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This is a research study. Research studies include only people who voluntarily choose to take part in the study. This consent form gives you information about this research which will be discussed with you in relation to your child. The consent form may contain words or a procedure that you do not understand as these relate to your child. We urge you to ask questions about anything that is unclear to you. You will receive a copy of the signed and dated consent form to keep for your files.

1. Purpose of the Research: The Division of Cardiology is conducting a voluntary heart health screening study, entitled The Student Athlete Cardiac Evaluation Registry. The goal of the study is to determine whether a student athlete is currently at high risk for sudden cardiac death, requiring further testing or stopping participation in athletics. Sudden cardiac death is caused by an irregular heart rhythm from the lower chambers of the heart, which often leads to death if not treated promptly. There are various heart abnormalities which put athletic participants at risk for sudden cardiac death and these abnormalities will be specifically searched for in the screening study. In addition, measurements such as neck size, body size (body mass index), may put a person at risk for heart disease in the future. The screening will make these measurements, make the results available to you and, if needed, have your child follow up with your primary doctor to make lifestyle changes before heart disease occurs. Approximately 300 to 500 student athletes will be enrolled in the study.
2. Procedures to be Followed: If you agree to participate in this research, your child will have the following tests and procedures performed as part of a health screening:
 - You will be asked to complete a questionnaire about your child's medical history and whether symptoms have been present during athletic participation or exertion. In addition, there is a section on family history for heart problems.
 - Your child's blood pressure will be measured using standard techniques. A blood pressure is taken with a blood pressure cuff applied to the arm and the technician will use a stethoscope to determine blood pressure readings.
 - Your child will have height and weight measured. In addition, neck, waist and hip size will be measured. Body mass index and percent body fat will be measured with a noninvasive device (your child will stand on the machine and measurements are taken).
 - Your child will undergo a standard cardiac physical examination. This will be performed by medical doctors who have volunteered to work during this study. The physical examination involves evaluating the child's pulses, listening to the heart and lungs with a standard stethoscope.
 - Your child will have an electrocardiogram which is a test that measures the electrical activity of the heart. For this test, your child will lie down and a technician will place several patches

or electrodes with gel on the chest, arms and legs. The electrodes are connected to wires called leads which are connected to an EKG machine. The electrical activity of the heart will be recorded on a strip of paper in the electrocardiogram machine.

- Your child's data will be reviewed by one of our volunteer physicians. If appropriate, an echocardiogram will be ordered and performed at the same time. An echocardiogram takes pictures of the heart in motion using ultrasound waves. Your child will lie down and a technician will place sensors like the ones used for the ECG on the chest. A gel is then applied to the chest and the echo transducer (ultrasound probe) is placed on top of the gel. The echo technician then makes recordings from different parts of the chest to obtain several views of the heart.
- The results of your child's screening examinations will be sent to you.
- RWJUH-Somerset will assign each child a unique identifier number and the data will be kept in a secure place..
- If it is felt that your child has an abnormality that might put them at increased risk for sudden cardiac death, this will be explained to you at the end of the screening. We will provide you with the names of cardiologists in the local area where a full comprehensive heart examination and evaluation can be performed. You are also free to choose your own cardiologist. Further evaluation will be your choice and should be billed to your health insurance provider. The results of your child's test will also be available to his or her primary care physician.

3. Discomforts and Risks: There is no risk. All devices used for your child's screening are FDA approved and all procedures are standardized according to national guidelines and performed by trained/ licensed personnel. Should any injury occur as a result of participating in this study, it will be evaluated and treated by the physicians on site during the screening at no cost to you.

Limitations of Screening: The major purpose of the Student Athlete Cardiac Evaluation Registry is to learn if there are early signs of heart abnormalities that might not have been known to be present before the screening took place. The screening will look for the major abnormalities known to cause sudden cardiac death. However it does not screen for everything. For example, echocardiographic screening can miss some disorders of the aorta. In addition, the screening study may not evaluate for the presence of coronary artery disease (a blockage in a heart artery or a heart artery that comes off the aorta in an unusual place). These conditions can also cause sudden cardiac death in student athletes but are very rare and involve testing that is beyond the scope of screening studies.

In addition, some serious heart conditions evolve over several years and may therefore be missed by one isolated screening evaluation. We cannot guarantee that every student who may experience sudden cardiac death will be identified.

- Possible Benefits to You: The benefit of the study will be that you will receive a summary of the test results and be able to share the summary with your primary care physician. If there is an abnormality that places your child at a higher risk for sudden cardiac death, that will be conveyed to you at the end of the screening. However, there is no guarantee that your child will benefit from participating in this research. By agreeing to participate in this research, your child is giving permission to RWJUH-Somerset Department of Cardiology to collect and analyze the health information provided. The information may be reviewed at a tertiary care center to utilize their expertise in screening for these types of heart abnormalities. If these results are reported to the medical and scientific community in the form of scientific, oral, written or electronic presentations, no personally identifiable information will be shared.

4. Right to Ask Questions: You have the right to ask any questions you may have about this research. If you have any questions or concerns later or if you believe your child may have

developed an injury that is related to participating in this research, you can contact Dr. Steven Georgeson at 908-526-8668 or Dr. Mark Lebenthal at 908-722-6410.

If you have questions regarding your child's rights as a research participant, you may contact John Bucek, MD, Chairman of the Institutional Review Board at RWJUH-Somerset at: 908-243-8652

5. Reimbursements and/or Costs for Participation: There will be no reimbursement to you for your child's participation in this program. The cost of all the screening tests and related procedures involved in this research are covered by RWJUH-Somerset. There will be no cost to you or your child for participating in the screening program.

You are not waiving any legal rights for you or your child by signing this form.

6. Voluntary Participation: Taking part in this research study is voluntary. If you choose to allow your child to take part in this research, your major responsibilities will include completing the health questionnaire and taking the time to have the other tests listed above. Your child does not have to participate in this research. If you choose to have your child take part, you have the right to stop at any time. If you decide not to have your child participate or if you decide to stop your child from taking part in the research at a later date, there will be no penalty or loss of benefits to which you or your child are entitled. In other words, your decision not to have your child participate in this research or to stop taking part in this research will not affect your child's medical care.

Signature and Consent to be in the Research:

Your signature below means that you have read all the information about this research study, that you have had adequate time to ask all your questions and they have been answered to your satisfaction. By signing this consent form, you indicate that you are voluntarily choosing to allow your child to take part in the research.

Print Name	Signature	Date
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Student's Name	Relationship granting legal authority
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Printed Name of person obtaining consent	Signature	Date
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Initials _____