

# Participant Information Statement

## *Sporting organisations*



### ***Research Study: The Australasian Registry for ECGs of National Athletes (ARENA) Project***

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#### **1. What is this study about?**

This study is being conducted to develop a registry of athlete cardiac screening ECGs to centralise cardiac screening data from across elite sporting organisations in Australia and New Zealand to facilitate current and future research. Cardiac screening of elite athletes for conditions associated with sudden cardiac death (SCD) is now widely recommended by leading bodies such as the Australasian College of Sport and Exercise Physicians (ACSEP). Screening generally includes a personal and family history and a physical examination, together with a resting 12-lead electrocardiogram (ECG). Some sporting organisations also include other tests, such as echocardiogram.

Most Australian and New Zealand sporting organisations are already screening athletes. However, the data that is collected is not structured to be shared, meaning few comparisons exist across different sports. In addition, diverse ethnic groups and female athletes are under-represented in research that informs current guidelines.

The Australasian Registry of Electrocardiograms of National Athletes (ARENA) project aims to provide long-term national data which will be analysed to improve our understanding of:

- cardiac outcomes of screened athletes;
- the role of various ethnicities, age and sex in terms of accurate athlete ECG interpretation as these groups are under-represented in current guidelines; and
- the bounds of normal cardiac adaptations to exercise across athletes from different Australasian sports to provide relevant benchmarks for normal athlete ECG features and accurate interpretation.

The ARENA project has been endorsed by the ACSEP and Sports Medicine Australia (SMA).

Taking part in this study is voluntary. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

#### **2. Who is running the study?**

The study is being carried out by:

*Registry director and chief investigator:*

- A/Prof Jessica Orchard, Registry Director and Principal Research Fellow, School of Public Health, The University of Sydney

*Co-investigators and clinical advisors, including:*

- Dr John Orchard, Adjunct Professor, Sydney School of Public Health, The University of Sydney; Sport and Exercise Physician; Chief Medical Officer, Cricket Australia

- Professor Andre La Gerche, Sports Cardiologist, St Vincent's Hospital Melbourne; Lab Head, St Vincent's Institute, Melbourne
- Professor Rajesh Puranik, Cardiologist, Royal Prince Alfred Hospital; Clinical Professor, The University of Sydney
- Associate Professor Hariharan Raju, Cardiologist and Electrophysiologist; Macquarie University
- Dr Simon Eggleton, Cardiologist, Prince of Wales Hospital
- Professor Tim Driscoll, Professor of Epidemiology and Occupational Medicine; Sydney School of Public Health, The University of Sydney

This study is being funded by an Australian Government National Health and Medical Research Council (NHMRC) Investigator Grant.

### 3. Who can take part in the study?

Any elite sporting organisation in Australia and New Zealand that conducts cardiac screening of athletes that includes a resting 12-lead electrocardiogram (ECG).

### 4. What will the study involve for my sporting organisation?

If your sporting organisation decides to take part in this study, you will then be asked provide data for athletes who have undergone cardiac screening with your sporting organisation. This includes an initial data collection of previously completed screenings since your policy commenced (retrospective data), and future screenings going forward (prospective data).

#### *Retrospective data – opt-out consent process*

For the initial collection of retrospective AIS data, consent will be opt-out. This means that athletes' data will be included unless they choose to opt out. Any athlete wishing to receive additional information about the Registry or to opt out can find further details in the Athlete Participant Information Statement (PIS) or flyer, which are available [online](#) or from the research team.

#### *Prospective data – opt-out consent process*

Consent for prospective data will be opt-out. You will be provided with a flyer to be made available to athletes and verbal script to read to athletes undergoing screening, which briefly explains the project. For any athlete who would like more information, or to opt out, the Athlete PIS and the flyer provides these details and will be supplied to you (and are available [online](#)). The Athlete PIS and flyer will also be shared with Players' Associations.

Prospective data will be collected annually or at a frequency that suits you, and will be at least 6 months after screenings have been completed to allow time for any required follow-up to be completed.

#### *Data to be collected*

Your sporting organisation will be asked to provide data for each athlete including **name, sex, ethnicity (if available), date of birth, sport/distance/event, date and result of each cardiac screening, a copy of the ECG and any other cardiac tests/reports (e.g. echocardiogram), whether follow-up tests were required and the outcome, any cardiac diagnosis, and any major adverse cardiac events**. This information is necessary to accurately link screenings to the correct athlete and any previous records, identify duplicates, and add any outcomes later.

On request, you are welcome to review draft publications involving your sporting organisation prior to submission for publication.

## 5. What will happen to information that is collected?

Data will be securely stored at the South Australian Health and Medical Research Institute (SAHMRI). By providing your consent, you are agreeing to us collecting information from your sporting organisation for the purposes of this project. We will ask your sporting organisation to sign a Data Transfer Agreement with the University of Sydney and SAHMRI which sets out the details of information collection, protection and permitted use. All information will be kept confidential and safety measures are in place to protect this information.

De-identified information (only) will be used for analysis and research purposes, and results will be published. Athletes will not be identifiable in these publications, although (if you agree) we may identify your sporting organisation as a participant. De-identified data may be used for other research projects and may be shared with other national and international collaborators, subject to the Registry's data sharing policy. Applications under the Registry's data sharing policy will be managed by the Steering Committee and subject to strict protections, including the requirement that any project seeking access to data have ethics approval and secure data storage procedures in place.

Data may be linked to other health datasets to enhance the Registry's ability to study and improve athlete cardiac outcomes.

The data collected will be re-identifiable. **Once the information is entered into the Registry, it will be given a unique identification number which links to each athlete's name and date of birth.** The code list will be stored separately. Access to re-identifiable information will be limited to the Registry Director and SAHMRI Registry personnel allocated to the project. **Data will be re-identifiable only for the following purposes:** to link multiple screening results from the same athlete or to identify duplicates; to add later outcome data to an athlete in the Registry (e.g. details of a cardiac diagnosis, cardiac-related retirement or sudden cardiac arrest) including potentially linking to another registry or database; if a previously unrecognised ECG abnormality is noticed by the Registry team; if an athlete later requests their data be withdrawn; or on request of the sporting organisation/athlete.

In the rare event that a previously unrecognised ECG abnormality is noticed by the Registry team, we will contact the chief medical officer of your sporting organisation by email and they will then contact the athlete and determine the appropriate follow up. Within 2 weeks of the first email, we will contact the chief medical officer a second time to confirm that they have received the notification.

On request, we are able to provide your sporting organisation with feedback on your cardiac screening program based on the information you provide.

## 6. Can I withdraw once I've started?

Being in this study is completely voluntary and you do not have to take part. Your decision will not affect your current or future relationship with the researchers or anyone else at The University of Sydney.

If you decide to take part in the study and then change your mind, your sporting organisation can withdraw at any time by contacting A/Prof Jessica Orchard ([jessica.orchard@sydney.edu.au](mailto:jessica.orchard@sydney.edu.au)). If you choose to withdraw, we will not collect any more information from you. Please let us know at the time you withdraw what you would like us to do with information we have collected from your

sporting organisation up to that point (noting that data that have already been published cannot be withdrawn).

**7. Are there any risks or costs?**

Aside from giving up your time in providing data, we do not expect that there will be any risks or costs associated with taking part in this study.

**8. Are there any benefits?**

Your sporting organisation's participation in this study will be an important contribution to research on athlete cardiac outcomes (and the utility of cardiac screening) and could lay the foundation for a more standardised and streamlined best practice model for screening across sports, with the ultimate goal to improve preventive cardiac care and prevent sudden death in young athletes.

Participation will also contribute to quality improvement (by providing a 'double check' on ECGs and completeness of follow-up). Medical staff from your sporting organisation may be eligible for continuing medical education points for participating in a clinical audit and/or peer review activity.

**9. Will I be told the results of the study?**

You have a right to receive feedback about the overall results of this studies in this project. We will provide these to you in the form of a brief lay summary, together with a copy of any published research papers.

In addition, we are happy to provide customised feedback for your sporting organisation if you would like. This would include a summary of aggregate data for screening results, including the proportion of athletes screened, the proportion requiring follow-up, and any differences between groups (e.g. male vs female).

**10. What if I would like further information?**

When you have read this information, the following researcher/s will be available to discuss it with you further and answer any questions you may have:

A/Prof Jessica Orchard

Email: [jessica.orchard@sydney.edu.au](mailto:jessica.orchard@sydney.edu.au)

Phone: +61 2 8627 1664

Dr John Orchard

Email: [john.orchard@sydney.edu.au](mailto:john.orchard@sydney.edu.au)

Phone: +61 2 9351 8118

**11. What if I have a complaint or any concerns?**

The ethical aspects of this study have been approved by the Human Research Ethics Committees (HRECs) of The University of Sydney (Project No. 2023/551) and the Australian Institute of Sport according to the *National Statement on Ethical Conduct in Human Research (2007)*.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the University:

Human Ethics Manager

[human.ethics@sydney.edu.au](mailto:human.ethics@sydney.edu.au)

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***This information sheet is for you to keep***