

# PARTICIPANT INFORMATION SHEET



## **General Guidance**

Information sheets should be written in simple, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs with clear sub-headings to make the text manageable, and a font size for easy reading. As a general guide the language level used should be no more difficult than that used in tabloid newspapers. Large sections of unbroken text should be avoided and bullet pointed lists used where appropriate.

The tone should be invitational and not coercive or overly persuasive.

For the first page use headed paper of the institution where the research is being carried out. The title of the study and the researcher's name should be clear with contact details for further information provided. In the interests of safety LJMU ethics committee would advise researchers not to include home addresses or personal telephone numbers (mobile or home) as contact details for participants.

All consent forms and information sheets should be version dated in the header/footer to ensure that the most recent version is used and the pages numbered eg 2 of 3.

The participant should be given a copy of the information sheet for further reference and a copy should be retained by the researcher with the study documents.

## **Information for children**

When designing information sheets for children researchers need to consider the likely attention span of the child and any possible fear/apprehension of the procedures involved.

Consideration should be given to the possible need for reading out the information or the use of pictures to help explain certain details.

## **Relevant information**

The information sheet should include information on the following as a minimum:

- The purpose of the study
- What will happen to the participants

- Any risks involved in participation
- Details of how confidentiality will be ensured
- A clear statement that participation is voluntary and that they are able to withdraw at any stage

Where applicable the following information should also be included:

- Any payments which will be made to participants
- What will happen to any personal information (eg identifiable details, video or tape recordings)
- Any details relating to possible disclosure of information
- Who they can contact if there is a problem
- For interventional studies details of any insurance/indemnity in the event of negligent/non-negligent harm
- Details of any research sponsor or funder particularly where this may lead to a conflict of interests
- Where human tissue samples are to be donated by the participant the following information must be included:
  - details of why the tissue samples are being collected
  - brief details of the proposed tests and analyses to be performed
  - details of how the tissue will be stored and disposed of
  - where consent is being sought for future, undefined research a brief statement of what types of research the tissue may be used for should be included
  - any procedures for possible feedback of individually significant information from their use

Where applicable participants must be given specific information relating to the following potential uses of tissue samples or personal data:

- Export for use in research outside the UK
- Animal research
- Research involving human embryos and stem cells
- Research into termination of pregnancy or contraception
- Research involving genetic analysis
- Commercial research (it should be made clear to participants that in the event of the development of a new product or service there will be no personal financial gain)

# LIVERPOOL JOHN MOORES UNIVERSITY PARTICIPANT INFORMATION SHEET



## **Title of Project**

**The impact of prolonged exercise on cardiac function and markers of cardiac damage in Lakeland 50 mile and Lakeland 100 mile ultra endurance race competitors**

**Chris George (MSc Sports Physiology, RISES, Faculty of Science)**

*You are being invited to take part in a research study run by Christopher George from the Research Institute of Sport & Exercise Sciences (RISES). Before you decide it is important that you understand why the research is being done and what it involves. Please take time to read the following information. Ask us if there is anything that is not clear or if you would like more information. Take time to decide if you want to take part or not.*

### **1. What is the purpose of the study?**

*Recent studies have suggested that prolonged endurance exercise may be associated with a transient decrease in cardiac function and appearance of blood borne markers of cardiac damage. Whether these issues are related and how performing endurance activity of different durations impacts upon this data is not known. Consequently the aim of our study is to assess cardiac function (via echocardiography) and cardiac biomarkers in the blood before and after completion of the Lakeland 50 mile and Lakeland 100 mile challenge.*

### **2. Do I have to take part?**

*This study is entirely voluntary, and it is up to you to decide whether or not to take part. If you do you will be given this information sheet and asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw will not affect your rights/any future treatment/service you receive.*

### **3. What will happen to me if I take part?**

*Subjects will be required to lay down on a bed to receive an echocardiography scan of the heart (diagnostic technique using ultrasound to image the heart), and for a 5 ml venous blood sample taken from the arm (for measurement of markers of*

cardiac fatigue) This will be done before and on immediate completion of the run.

Other measurements of height, weight, blood pressure and heart rate will be collected at rest both before and after the run.

The research testing will last approximately 30 minutes prior to the race and c. 20 minutes post-race. The longer pre-race test is because we will also ask questions about your training and competition history.

#### **4. Are there any risks / benefits involved?**

It is possible that you may get mild level of discomfort and bruising from blood sampling as it requires a needle to be inserted into the arm. However, trained and experienced phlebotomists will be taking the sample, making the procedure as comfortable as possible. All other tests are non-invasive and performed at rest.

#### **5. Will my taking part in the study be kept confidential?**

Your confidentiality will be maintained throughout the study. The results achieved will not be personally identifiable to the subject, shared with any third party, or stored for unrelated analysis.

#### **Contact Details of Researcher**

For further details please contact Christopher George  
C.George@2005.ljmu.ac.uk

*Note: A copy of the participant information sheet should be retained by the participant with a copy of the signed consent form.*