

**PARTICIPANT INFORMATION SHEET – CASES**

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| **Title** | **Investigating heat tolerance in females** |
| **Short title** | Heat Tolerance in Females |
| **Approval number** | DDVA HREC/OUT/2019/BN481007 |
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This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about.

Participation in this research is entirely voluntary; there is no obligation to take part in the study, and if you choose not to participate there will be no detriment to your career or future health care.

If you decide you want to take part in the research project, you will be asked to sign the consent section.

You will be given a copy of this Participant Information and Consent Form to keep.

**Brief description of the study**

CLINICAL REFERRAL – HEAT TOLERANCE TEST (STANDARD TEST)

You have been referred for a heat tolerance test (including assessment of rectal temperature) because your physician believes you may have suffered heat stroke. The outcome of your heat tolerance test will be reported back to your referring physician and the test outcome may affect your Defence career.

INVESTIGATING HEAT TOLERANCE IN WOMEN (RESEARCH STUDY: OPTIONAL)

The aim of this study is to investigate heat tolerance females. Heat tolerance testing is performed following a known or suspected case of heat stroke to identify if a person is heat intolerant (someone who struggles to maintain body temperature in hot conditions). There is a standard heat tolerance test protocol that was developed in the late 1970s with male participants and it is used worldwide to diagnose heat intolerance. The heat tolerance test is commonly used by occupational groups such as the military where it is used to decide if someone is fit to return to duty following heat illness. As the majority of research into heat has been performed with male participants, less is known about female heat tolerance. This study will therefore investigate female responses to the heat tolerance test.

The standard heat tolerance test includes assessment of rectal core temperature, heart rate, skin temperatures, sweat rate (via body weight), hydration status and ratings of exercise effort, thermal comfort and thermal sensation during 2 hours of treadmill walking in hot conditions. The research study will include the standard heat tolerance test plus gastrointestinal core temperature pill assessment during the heat tolerance test and a VO2max fitness test the day before the heat tolerance test. Details of these procedures are included below and in Figure 1.

The results of this research will be used by *Faith Alele* to obtain a *Doctor of Philosophy* degree.

**What does participation in this research involve (See Figure 1 below)?**

* You will be considered ‘on duty’ whilst participating in this study.
* Initially you will undergo a medical pre-screening process including a questionnaire and measurement of resting heart rate and blood pressure and be given clear instructions on the procedures involved in the heat tolerance test. Blood pressure will be checked with a standard arm-cuff monitor and if it is high (>140/90 mmHg) after two readings we will not go ahead with the heat tolerance test until medical clearance is obtained from a doctor.
* A day before the heat tolerance test, you will attend the laboratory for about 30-45 minutes to have your aerobic fitness assessed using a VO2max test. The test involves exercising on a bike or a treadmill starting at low intensity that increases every few minutes until you can’t go any longer. A face mask will be used to allow us to measure your breathing.
* You will then be asked to provide a mid-stream urine sample to establish adequate hydration status. If you are dehydrated, you will be given water to consume followed by a second urine sample before the test can begin. Additionally, hydration status will also be assessed by Bioelectrical Impedance analysis where a very mild electrical current passes through the body. Nude body weight will be assessed in a private cubicle to allow for the accurate assessment of sweat rate.
* Assessment will be made of skin temperatures from the arm, chest and leg via small buttons taped to the skin. Core body temperature will be assessed rectally and via a gastrointestinal core pill ingested 6-8 hours before the test. You will insert your own rectal probe in a private cubicle. Core and skin temperatures will be assessed at regular intervals throughout the heat tolerance test. We aim to compare the rectal and gastrointestinal core temperature. This will remove the need to use a rectal probe in future heat tolerance tests and minimise the invasiveness of the heat tolerance test.
* The heat tolerance test will take place in a climate control chamber under hot, dry conditions (40°C and 40% relative humidity). The protocol involves light exercise on a treadmill at 5 km/hr and 2% elevation for 120 min. You should be dressed in PT gear (shorts, T-shirt and running shoes). Heart rate will be constantly monitored using a standard Polar heart rate monitor strapped around the chest. At regular intervals during the test we will ask you to rate how warm the environment feels; how comfortable you feel in the environment and how hard the exercise feels. There will be number scales explained to you to make these ratings.
* A VO2 test will be conducted during the heat tolerance test (while walking on the treadmill). The test will involve assessing your VO2 for three to four minutes every half hour during the heat tolerance test
* There will be access to drinking water at all times during the protocol inside the chamber.
* Body weight will be measured after completion of the test followed by a second urine sample to assess hydration status. The total time required to perform the test is 3-4 hours.
* If the protocol is inappropriate for women, a revised protocol will be developed, and you will be invited to repeat your heat tolerance test to evaluate the revised protocol.

**Withdrawal from study and data withdrawal**

You may withdraw from the study, for any reason with no impact on the conduct or outcome of your heat tolerance test. Please notify Faith Alele, or other researchers, within fourteen (14) days of having completed your participation in the study should you wish to withdraw from the study. Please note, the clinical diagnosis from your heat tolerance test will be reported back to your referring physician regardless of whether you volunteer or withdraw from the study. An unfavourable outcome (i.e. heat intolerant diagnosis) may affect your deployability in accordance with Defence health policy. Your research data would be withdrawn from the study should you decide to withdraw.

**Benefits**

Your participation in this study will contribute to further understanding heat tolerance in females. The majority of research to date has focussed on heat tolerance in males and female heat tolerance is less well understood. Research has shown that females have different responses to heat and therefore their response to the heat tolerance test may be different.  With increasing numbers of females serving within the Defence Force, your participation in this study will also benefit future female Defence members.

**Risks of participating**

There will be some discomfort and fatigue at the end of the aerobic fitness test (VO2max test) as this test requires reaching your maximum exercise capacity. It is the same feeling as the end of a beep test which you have likely experienced during your Defence fitness assessments. This includes breathing hard, some muscle soreness and fatigue. However, recovery from this test is usually quick.

Please note that you may experience symptoms of heat illness during the heat tolerance test including headache, fatigue, dizziness or light-headedness, muscle weakness or nausea. Should you experience any of these symptoms during the test you should immediately report them to the researchers conducting the test. The researchers will remind you of these symptoms prior to the start of the test and enquire whether you are experiencing any of these symptoms at regular intervals during the test. The VO2max test may be associated with feelings of fatigue, exhaustion and discomfort, particularly towards the end of the test. However, recovery from the test is very rapid.

The gastrointestinal core temperature pills are approximately the size of a medium-large tablet or capsule and should be swallowed approximately 6-8 hours prior to the heat tolerance test. The pills transmit data on gut temperature to a monitor held within one metre of the body. The strength of the electro-magnetic signal of the pill is weaker than that associated with using a personal computer. The pill is covered in a Silicone coating that is not affected by passage through the gut. All pills are sterile before use and are for single use only. The pills have been used in teaching, research and consultancy activities by staff at the JCU Institute of Sport and Exercise Science for over 10 years with no negative effects in this time. The core pills are also used by many other scientists in Australia. There exists a minor risk of choking on the pill, therefore we advise that you swallow the pill in the presence of another person. There is also a theoretical risk of the pill lodging elsewhere in the gastrointestinal tract, although, of more than 17,000 of these pills sold, there has been only one recording of a lodgement, and it involved a person who had had previous gastrointestinal surgery. We will therefore ask you a number of questions regarding your gastrointestinal health prior to participating in the study so that anyone with a known disease or disorder of the throat or gut does not participate in the study.

**Safety during testing**

The heat tolerance test will be stopped if your core temperature exceeds 39.5°C or should you report or exhibit symptoms of heat illness. All staff involved in this study are qualified in First Aid and cardio-pulmonary resuscitation (CPR). Essential medical equipment is also kept in the laboratory and telephone access is available in case of an emergency.

**Privacy and confidentiality**

The data collected during your heat tolerance testwill include both hand written records and computer files. The hand-written records will be stored in a locked filing cabinet in a locked office. The electronic files will be kept on a password protected computer in a locked office. The data will be kept securely for a minimum of 15 years after the study has been completed and may be used for future research related to this study. Only the investigators will have access to the data. Your referring physician will receive a clinical report with a summary of the clinical data independent of the research study. Your data will be treated confidentially, and your anonymity preserved in any reports or published articles. No individuals or their Barracks will be identified in any report or publication of the data.

**Guidelines for Volunteers**

You will be provided with a copy of the of the Departments of Defence and Veterans' Affairs (DDVA) Guidelines for Volunteers which can also be found at the following website: <http://www.defence.gov.au/Health/HREC/docs/20180326-Guidelines_for_Volunteers.pdf>

**Dissemination of research findings**

It is anticipated that the results of this research project will used for Faith Alele’s thesis and published in journal articles. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. In addition, you will be provided with a copy of the research findings upon your request. A de-identified summary report of the findings will also be presented to the Australian Defence Force.

**Concerns or complaints**

Should you have any complaints or concerns about the manner in which this project is conducted, please do not hesitate to contact the researchers, Faith Alele or Dr Crowe, via the contact details on page one of this document, or you may prefer to contact the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) at the following address:

**Executive Officer, DDVA HREC**

Telephone: (02) 6266 3807
Email: ddva.hrec@defence.gov.au

Figure 1: Flow chart showing the process of participation in the study

**Pre-test**:

\* Check resting blood pressure, heart rate, baseline weight, height and temperature. \*Collect urine sample

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Standard heat tolerance test

Research study (includes core pill for temperature assessment)

Standard heat tolerance test

+

Conduct heat tolerance test

Conduct heat tolerance test + relative VO2

**Post-test:**

\*Check weight, temperature and collect urine sample

**Post-test:**

\*Check weight, temperature and collect urine sample.

Participate in the research study

Yes

No

Arrive at the climate control chamber

Arrive at the climate control chamber

Participate in the research study

Controls

Cases

Yes

No

Exclude

If protocol is found to be inappropriate

A revised protocol will be developed

**Day 1**:

\*Oxygen consumption test (VO2Max test)

**Day 2**

**CONSENT FORM**

|  |  |
| --- | --- |
| **Title** | Investigating heat tolerance in females |
| **Short title** | Heat Tolerance in Females |
| **Protocol number** | DDVA HREC/OUT/2019/BN481007 |

I, ................................................................………………... understand that I have been referred for a heat tolerance test. I also understand that I have the option to volunteer my heat tolerance test data to be used in the heat tolerance testing study.

I give my consent to participate in the research study mentioned above on the following basis:

The aims of this research project have been explained to me and how it will be conducted and my role in it.

I understand the risks involved as described in the Participant Information Sheet.

I am cooperating in this project on condition that:

* The information I provide will be kept confidential
* The information will be used for this study and other future related projects
* The research results will be made available to me at my request and any published reports of this study will preserve my anonymity.
* I have been given a copy of the ‘Departments of Defence and Veterans’ Affairs Human Research Ethics Committee (DDVA HREC) Guidelines for Volunteers’.

<http://www.defence.gov.au/Health/HREC/docs/20180326-Guidelines_for_Volunteers.pdf>

I understand that:

* I will undergo a standard heat tolerance test as referred by my physician and as part of the research study, I will also undergo a VO2max fitness test and relative V02 and core temperature assessment via a gastrointestinal core temperature pill if I choose to participate in the research study.
* There is no obligation to take part in this research study.
* I will be considered ‘on duty’ while participating in this study.
* If I choose not to participate in the research study there will be no detriment to the conduct or outcome of my heat tolerance test, my career or future health care.
* I am free to withdraw at any time any time during the study and up to 14 days after I complete the study with no detriment to the conduct or outcome of my heat tolerance test, my career or future health care.

I have been given a copy of the information/consent sheet, signed by me to keep.

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\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name in full

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