## RMIT University

# The Participant Information and Consent Form (PICF)

***INVITATION TO PARTICIPATE IN A RESEARCH STUDY***

**PARTICIPANT INFORMATION**

**Project Title*:*** *Exploring Physiological and Metabolomic changes with sauna and exercise*

**Research Investigators**

***Principal Investigators Student Investigator***

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Dear Participant,

You are invited to participate in a research project being conducted by RMIT University at the QAS (Queensland Academy of Sport), 468 Kessels Road, Nathan Qld 4111. This is because you have indicated interest in helping to contribute to research about lifestyle changes for optimal health and wellness.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. 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 strictly voluntary. If you don’t wish to take part, you don’t have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

 • Understand what you have read

 • Consent to take part in the research project

 • Consent to have the tests and treatments that are described

 • Consent to the use of your personal and health information as described.

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

***Who is involved in this research project?***

This study is being undertaken by Dr Joy Hussain as part of her postgraduate research studies in complementary medicine at RMIT University, under the supervision of Professor Marc Cohen and Associate Professors Ronda Greaves and Nitin Mantri, to better understand the effects of lifestyle changes like sauna on health. Other researchers are involved to provide high-level expertise in specific analysis of the collected bodily fluids. This project has been approved by the RMIT and the University of Queensland Human Research Ethics Committees. We expect up to 30 people to take part in this study.

***Why have you been approached?***

You have been approached because you have expressed interest in participating in our research. You are eligible to participate in this research trial if you are:

* A non-smoker and aged between 18-40 years
* Are willing and able to engage in sauna activities (both far-infrared and Finnish-style)
* Are willing and able to engage in 30 minutes of moderate-intensity exercise (stationary bicycle)
* Are willing to avoid over-the-counter medicines such as Nurofen and Paracetamol for 24 hours prior to the study sessions.
* Are willing to avoid perfumes and skin lotions/creams for 24 hours prior to the study sessions.
* Are willing to fast overnight for at least 10 hours prior to the study sessions.
* Understand all the information and have signed the written informed consent

You are **NOT** eligible if you:

* Smoke
* Take any medications or supplements on a regular basis (except ‘the pill’ or oral contraceptive)
* Have any chronic medical condition (i.e. diabetes, hypertension, atrial fibrillation, cardiovascular disease or previously diagnosed history of renal, cardiac, gastrointestinal, liver, psychiatric, skin or other medical disorder such as Raynaud’s syndrome)
* Have been regularly sauna bathing during the past 6 months
* Have been regularly exercise training (i.e. triathlon, marathon, etc.) vigorously for more than 60 minutes daily during the past 6 months
* Pregnant or expect/attempting to become pregnant or impregnate
* Currently have irregular menstrual periods
* Unable to give consent

***What is this study about? What are the questions being addressed?***

The purpose of this research is to investigate the changes in cardiovascular function and contents of sweat and urine in healthy young adults after a single session of Finnish, traditional-style sauna, far infrared sauna and exercise.

Some of the questions being addressed include:

* What are the different patterns of heart rate variability associated with sauna versus exercise activities?
* Is sweat produced while exercising similar in metabolic or toxicant content as sweat produced in different types of sauna?
* How long does it take to work up a sweat in different types of sauna? Is it the same as exercising at a moderate level?

You will be participating in a randomised cross-over study. In a ‘cross-over study’, the participants each have the different treatments (2 types of sauna and exercise) in turn and ‘randomised’ means the order of the different treatments will be determined by chance, not by you or the researchers. This means that you will not know which of the 3 activities after the initial control visit you will be asked to participate in until you arrive on each of the 3 days. This research has been designed this way to reduce bias and help make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid.

You are your own control group so all participants will complete an initial control intervention (resting) followed by the same 3 interventions, albeit in different orders.

We expect up to 30 participants to partake in this study.

***If I agree to participate, what will I be required to do?***

This study will require you to attend the Queensland Academy of Sport – main facilities at 468 Kessels Road, Nathan Qld 4111, on 4 separate morning sessions. You will be asked to fast from 10pm the night before each session, take a shower without soap or the use of any creams or lotions in the morning, drink at least 2 full glasses of water after awakening and arrive at 9:00am, and no later than 9:30 am, on the test mornings. Each session will take around 3 hours.

You will need to be dressed in a bathing costume and thongs or easily removable footware (without socks), comfortable enough to exercise in, with loose exercise shorts and t-shirt, with feasible access to sweat collection sites – forehead, inner wrist, underarms, lower back, lower thighs, calves and soles of feet. You will then undertake a series of tests before, during and after engaging in a designated activity.

During the first session, you will have the opportunity to get acquainted with the study site and equipment, ask any questions and then sign a consent form if you are happy to proceed and enrol in the study. You will then have your height and weight measured. Then you will be asked to provide a urine sample and then a doctor will take the following readings: skin temperature (from the 7 skin sites mentioned above with a non-invasive infrared thermometer), core body temperature (with a medical ear thermometer), blood pressure (with automated arm cuff device), and pulsoximetry (with a finger probe). Then a pulse wave velocity test using infrared technology will be conducted, taking around 1-2 minutes to conduct. Then you will be fit with 3 chest leads so that a baseline 10-minute reading of your continuous heart rate can be obtained.

**Session 1 – Initial Control Resting Intervention**

**INITIAL DISCUSSION: (approx. 30 min)**

→ Meet and greet; discuss participant information, consent form and answer any questions; conduct pre-intervention screen again.

→ Give tour of the parts of QAS facility where interventions are taking place.

→ Witness signing of consent form.

→ Assign order of next 3 interventions with computerised random sequence generator.

→ Complete pre-intervention survey.

**BASELINE CLINICAL ASSESSMENT: (approx. 30 min)**

→ Provide urine pot for participant self-collection; record urine dipstick results.

→ Measure height and weight and record results.

→ Measure tympanic core temperature; measure skin temperatures with infrared no-touch thermometer to 7 skin areas: forehead, inner forearms, axillary, lower back, anterior mid-thighs, posterior calves, soles of feet; record results.

 → Obtain blood pressure and pulsoximetry reading; record results.

→ Obtain pulse wave velocity reading; results recorded in equipment software.

🡪 Fit chest leads (3-lead heart rate monitor device) and chest belt (breathing rate device): start continuous heart rate variability and respiratory rate monitoring x 10 minutes; results recorded in associated equipment software.

**INTERVENTION: (**15 min + 5 min rest period + 15 min = 35-40 min total)

Encourage usual quiet resting activity (reading book/magazine, playing with smart phone, etc.)

 **FIRST 15 MIN:**

→ continuous heart rate variability and respiratory rate monitoring x 10 minutes with each beginning and ending 15 min-session; results recorded in associated equipment software.

→ record responses to mid-intervention survey questions (see attached)

→ record objective sweating state at set room temperature

**5 MIN REST PERIOD:**

→ repeat measurements of core body and skin temperatures x 7;

→collect 1st set ‘control sweat’ samples – artificial sweat (or mass spec-grade H20) sprayed onto 7 specified skin areas with gauze then applied to absorb ‘control sweat’ samples and record collection time and details.

→ obtain blood pressure and pulsoximetry readings; record results.

→obtain pulse wave velocity reading; results recorded in equipment software.

**SECOND 15 MIN:**

→ continuous heart rate variability and respiratory rate monitoring x 10 minutes with each beginning and ending 15 min-session; results recorded in associated equipment software.

→ record responses to mid-intervention survey questions

**POST INTERVENTION: (approx. 30 - 60 min)**

→ Collect 2nd set ‘control sweat’ samples – artificial sweat (or mass spec-grade H20) sprayed onto 7 specified skin areas with gauze then applied to absorb ‘control sweat’ samples;

→ Repeat measurements of core body and skin temperatures x 7;

→ Obtain blood pressure and pulsoximetry readings; record results.

→ Obtain pulse wave velocity reading; results recorded in equipment software.

→ Continuous heart rate variability and respiratory rate monitoring x 10 minutes; results recorded in associated equipment software. Remove chest leads (3) and chest belt.

→ Measure weight and record results.

→ Provide urine pot for participant self-collection; record urine dipstick results.

→ Complete post-intervention survey.

Then you will be asked to engage in a ‘control’ intervention resting activity for 35-40 minutes. Please bring a book, magazine or smartphone to keep yourself busy without any physical exertion during this resting ‘control’ activity. You will continue to have the chest leads in place taking 10-minute readings twice during this ‘control’ activity. You will be asked questions regarding your physical and mental state during these intervention activities.

During a 5-10 minute rest break (after 15 minutes of ‘control’ activity), you will have special ‘water’ squirted onto the 7 skin sites mentioned above with the water then absorbed by gauze that will be placed on the skin sites and then collected as ‘control sweat’ samples. During this same 5-10 minute rest break, you will also have your temperatures, blood pressure, pulsoximetry and pulse wave velocity readings taken again. You will also be given the opportunity to drink unlimited water (provided) at any point in the session if you should feel thirsty. The amounts you drink will be recorded.

After completing the remaining 15 minutes of the ‘control’ intervention, your body temperatures, blood pressure, pulsoximetry and pulse wave velocity readings will be taken again. The special ‘water’ will again be squirted onto the 7 skin sites, then absorbed by gauze that will be placed on the skin sites and then collected as a 2nd set of ‘control sweat’ samples. A final 10-minute reading of continuous heart rate/ respiratory rate will be obtained before removal of the chest leads and chest band. You will then be weighed again and asked to provide another urine sample. At the end of the session, snacks will be made available in addition to unlimited water. Please refer to Session 1 diagram for a summary.

The remaining 3 sessions involving each of the treatment interventions will happen in a random order and be scheduled at your convenience so that at least 48 hours to 1 week separates each of the remaining sessions. For example, one participant may be scheduled a week later for the exercise session, then in two weeks be scheduled for the Finnish, traditional style sauna intervention and then a month later, get scheduled the infrared sauna cabin session. Whereas another participant may be scheduled a month later for the infrared sauna cabin session, then the next week for the exercise session, then a week later the Finnish, traditional-style sauna session.

All the remaining sessions will involve the same timing and sequence of steps, except you will be sweating during the assigned intervention and there will be no need to squirt you with any water since your own sweat will be generated and then collected in the same manner. Please refer to ‘Sessions 2, 3, 4’ diagram for a summary of what to expect on the following 3 visits to QAS.

**Sessions 2, 3, 4 – Follow-up Interventions, randomly allocated order, with at least 48 hours – 1 week in-between each of the visits**

**DISCUSSION: (approx. 15 min)**

→ Complete pre-intervention survey.

→ Elicit feedback regarding last intervention.

**BASELINE CLINICAL ASSESSMENT: (approx. 30 min)**

→ Provide urine pot for participant self-collection; record urine dipstick results.

→ Measure weight and record results.

→ Measure tympanic core temperature; measure skin temperatures with infrared no-touch thermometer to 7 skin areas: forehead, inner forearms, axillary, lower back, anterior mid-thighs, posterior calves, soles of feet; record results.

 → Obtain blood pressure and pulsoximetry reading; record results.

→ Obtain pulse wave velocity reading; results recorded in equipment software.

🡪 Fit chest leads and chest belt: start continuous heart rate variability and respiratory rate monitoring x 10 minutes; results recorded in associated equipment software.

 **INTERVENTION:** (15 min assigned intervention + 5 - 10 min rest + 15 min assigned intervention = approx. 35 -40 min)

Assigned intervention will either be exercise on standing bicycle **OR** Finnish-style sauna bathing **OR** infrared sauna cabin bathing, only one intervention per visit/session.

**FIRST 15 MIN:**

→Continuous heart rate variability and respiratory rate monitoring x 10 minutes with each beginning and ending 15 min-session; results recorded in associated equipment software.

→ record responses to mid-intervention survey questions

→ measure and record ‘time to sweat’

**5 MIN REST PERIOD:**

→collect 1st set sweat samples – record collection time and details.

→ repeat measurements of core body and skin temperatures x 7;

→ obtain blood pressure and pulsoximetry readings; record results.

→obtain pulse wave velocity reading; results recorded in equipment software.

**SECOND 15 MIN:**

→ Continuous heart rate variability and respiratory rate monitoring x 10 minutes with each beginning and ending 15 min-session; results recorded in associated equipment software.

→ record responses to mid-intervention survey questions

**POST INTERVENTION: (approx. 30-60 min)**

→ Collect 2nd set sweat samples – record collection time and details;

→ Repeat measurements of core body and skin temperatures x 7;

→ Obtain blood pressure and pulsoximetry readings; record results.

→ Obtain pulse wave velocity reading; results recorded in equipment software.

→ Continuous heart rate variability and respiratory rate monitoring x 10 minutes; results recorded in associated equipment software. Remove chest leads (3) and chest belt.

→ Measure weight and record results.

→ Provide urine pot for participant self-collection; record urine dipstick results.

→ Complete post-intervention survey.

***What are the possible risks or disadvantages?***

We do not anticipate any additional risks to your normal day-to-day activities outside of usual risks associated with fasting overnight and participation in the activities of sauna bathing or moderate exercise on a stationary bicycle.

 A single session of sauna bathing can be associated with mild-to-moderate heat intolerance, nausea, headache, light headedness, blurred vision, dizziness, transient pains in arms/hands or feet/legs, difficulties breathing, skin rashes and/ or claustrophobia. If you experience any of these symptoms or other symptoms to the point of discomfort during any of the interventions, you will be encouraged to discontinue the sauna bathing and you will receive immediate medical attention. You will have a registered medical doctor, Dr Joy Hussain, nearby during all the sauna bathing sessions.

Engaging in moderate bicycling exercise can be associated with mild-to-moderate heat/sweating intolerance, pain due to potential muscular, ligamentous or tendinous injuries or impairments, falls off bicycle, airway irritation, and/or shortness of breath. Again, if you experience any of these symptoms or other symptoms to the point of discomfort, you will be encouraged to discontinue the bicycling and you will receive immediate medical attention. You will have a registered medical doctor, Dr Joy Hussain, nearby during all the exercise sessions.

If at any time you become upset or distressed as a result of your participation in this research, please communicate your concern to the study doctor and he/she will be able to arrange for counselling or other appropriate support. This can be provided by qualified staff who are not members of the research project team if you prefer. Your participation is purely voluntary, and you can withdraw from the study for any reason and at any time.

***What are the benefits associated with participation?***

This study may identify changes over time in your body physiology (temperature, heart rate variability, pulse rate, oxygen saturation, blood pressure, respiratory rate, etc.) and levels of various metabolites in your urine and/or sweat with sauna and bicycling activities. You will be given a free assessment report of your heart rate variability with each of the sessions after completion of the sessions.

***What will happen to the information I provide?***

The collected data and information gained from your participation will be analysed individually and pooled with data from other participants and reported as part of a PhD thesis to be published in peer reviewed journals and/or at scientific conferences. Your information will remain confidential at all times. Only de-identified and group results will be reported and at no time will any individual’s identified results be published. All these publications will be made available through the RMIT Repository in the reports as an Appropriate Durable Record (ADR), which is a publicly accessible online library of research papers.

All data and your consent forms will be kept securely at RMIT University for 15 years after publication before being destroyed. Only the published research papers will remain online.

***What will happen to my urine and sweat samples?***

Your urine and sweat samples will be collected, then transferred for metabolomic and/or toxicant analysis to the University of Queensland/ Queensland Alliance for Environmental Health Sciences and Pathology Queensland research laboratories. The analysis uses chromatography and mass spectrometry-based tools to determine levels of various environmental toxins (toxicants) in your urine or sweat. Once it has been analysed, your urine and/or sweat may be stored for a period of up to 5 years. During this time, your samples may be used for further testing, but your identity will be protected by labelling your samples with a code. University of Queensland/ Queensland Alliance for Environmental Health Sciences and Pathology Queensland will not sell your samples or knowingly transfer your samples to anyone who has expressed intent to sell the samples.

If enough sweat is collected, your sweat samples may be analysed at a later date for transcriptome changes at the RMIT University’s research laboratories in Bundoora, Victoria. This analysis uses RNA to measure your body’s metabolic activity at the time the sweat was taken. Once it has been analysed, your sweat may be stored for up to five years, after which time it will be disposed of according to standard laboratory practice. During this time, your samples may be used for further testing, but your identity will be protected by labelling your samples with a code. RMIT will not sell your samples or knowingly transfer your samples to anyone who has expressed intent to sell the samples.

***What are my rights as a participant?***

Participation in any research project is purely voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

***What if I withdraw from this research project?***

If you do withdraw your consent during the research project, the study doctor(s) will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

You also have the right to request any unprocessed data to be withdrawn and destroyed provided you are identifiable. You have the right to ask questions at any time about the study.

***What if I have complaints or complications participating in this research project?***

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

***Who is funding this research?***

RMIT University is funding this research. There is no corporate sponsorship.

The researchers declare no known conflict of interests. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

***Whom should I contact if I have any questions?***

In the event you have any questions regarding participation in this study please do not hesitate to contact Dr Joy Hussain by email – juhaina.joy.hussain@student.rmit.edu.au or by telephone - 0439 383 889. Alternatively, you can also contact the principal investigator, Professor Marc Cohen, whose contact information is provided on the first page of this information sheet.

*Yours sincerely,*

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*Dr Joy Hussain Professor Marc Cohen*

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*Associate Professor Nitin Mantri*

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*Associate Professor Ronda Greaves*

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HRECs of RMIT and University of Queensland.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

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| *If you have any concerns about your participation in this project, which you do not wish to discuss with the researchers, then you can contact the Ethics Officer, Research Integrity, Governance and Systems, RMIT University, GPO Box 2476V VIC 3001. Tel: (03) 9925 2251 or email* *human.ethics@rmit.edu.au* |



**CONSENT FORM**

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| --- | --- |
| **Project Title** | *Exploring Physiological and Metabolomic changes with Sauna and Exercise*  |
| **Short Title** | Sauna-Exercise Study |
| **Protocol Number** | ACTRN 12618000679280p |
| **Project Sponsor** | RMIT University |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Joy Hussain/ Professor Marc Cohen |
| **Associate Investigator(s)** | Dr Nitin Mantri, Associate Professor Ronda Greaves |
| **Location** | Brisbane |

**Declaration by Participant**

1. **I have had the project explained to me, and I have read the Participant Information Sheet.**
2. **I understand the purposes, procedures, benefits and risks of the research described in the project.**
3. **I have had an opportunity to ask questions and I am satisfied with the answers I have received.**
4. **I freely agree to participate in this research project as described in the Participant Information Sheet and I understand that I am free to withdraw at any time during the study.**
5. **I acknowledge:**
* **to undertake the tests or procedures outlined**
* **I have provided true and correct medical information to the best of my knowledge.**
* **I understand that my participation is voluntary and that I am free to withdraw from the project at any time and to withdraw any unprocessed data previously supplied.**
* **The project is for the purpose of research.**
* **The privacy of the personal information I provide will be safeguarded and only disclosed where I have consented to the disclosure or as required by law.**
* **The security of the research data will be protected during and after completion of the study.**
* **The data collected during the study may be published, however no information which can identify me will be used.**
* **I will be given a signed copy of this document to keep.**

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|  |
|  | **Name of Participant (please print)** |  |  |  |  |
|  |
|  | **Signature** |  |  **Date** |  |  |