

PARTICIPANT INFORMATION LEAFLET (PIL)

1. Introductory statement – invitation to take part

You are invited by researchers at University College Dublin (UCD) to take part in a research study.

This Information Leaflet tells explains what is involved if you agree to take part. Participation in this research is voluntary. If you do not wish to take part, you do not have to.

If you decide to take part in this research study, you will be asked to provide consent before participating. By doing so, you are confirming that you understand what is involved, that you agree to take part, and that you understand how your data will be used in this study.

2. Contact details:

Principal Investigator:

Dr Sinéad Holden
School of Public Health, Physiotherapy and Sports Science
University College Dublin

Email: sinead.holden@ucd.ie

Additional researchers:

The project is being run by researchers from UCD School Public Health, Physiotherapy and Sports Science, Insight Research Ireland Centre for Data Analytics, the Institute for Sport and Health and the School of Computer Science:

- Associate Prof. Brian MacNamee: brian.macnamee@ucd.ie
- Prof. Brian Caulfield: Brian.caulfield@ucd.ie
- Research Engineer: Evgenia Angelidi: Evgenia.angelidi@ucd.ie
- PhD Student: Eline de Jager at eline.dejager@ucdconnect.ie

3. Title of the research

Ovarian hormone profiles and heart rate variability tracking in female athletes: an anonymous data donation study

4. What is this research about? / Why is this study being done?

This study aims to better understand how heart rate variability (HRV) changes across ovarian hormone profiles (e.g. menstrual status, hormonal contraceptive use, reproductive life stages (pregnancy, menopause) in females.

Many females now use wearable devices and apps to track health and well-being/recovery information. However, there is still limited research on how hormonal changes may influence HRV patterns in females. This may be important for improving how wearable devices interpret data and provide feedback to female athletes.

This study will collect anonymous questionnaire responses and donated tracking data from female athletes who already monitor their menstrual cycle and/or HRV. The findings will help improve understanding of female athlete physiology and may potentially improve resources or guidelines around menstrual and health tracking for females.

5. Why have I been invited to take part?

You have been invited to take part because you are an adult female athlete, aged 18 years or older, and you may already use a wearable device or app to track menstrual cycle information and/or HRV.

6. Do I have to take part ?

No. You do not have to take part in this study. Taking part is entirely voluntary.

7. What will happen if I decide to take part in this research study? What do I need to do ?

If you decide to take part, you will be asked to:

- Complete a short online questionnaire.
- Optionally donate tracking data that you have collected through your wearable device and/or app.

The questionnaire will ask for general information relevant to the study, such as your age range, activity level, skin colour, and use of hormonal contraceptives.

If you choose to donate anonymous data, this may include wearable data such as HRV data, menstrual cycle data and temperature data. If you choose to donate data, this will be done through the CycleSync platform. You will be asked to securely connect your wearable account (e.g. Garmin) using a standard authorisation process. This connection happens directly between you and your device provider, and the research team will not have access to your login details.

You will be able to choose what data you wish to share and the time period for which data are shared. Only the data you select will be transferred to the research dataset. You can control the parameters for this at the time of donation.–The team will not collect or store any identifiable information. Participation is online and only takes a few minutes to complete.

8. Can I withdraw from the study? What happens if I change my mind ?

You are free to stop participating at any time before you submit your data. Because this is designed as an anonymous study, once you have submitted your data, it **will not be possible for the research team to identify your data** to remove it. This is because no direct identifiers or potentially identifying information is collected.

9. What are the benefits of my participation in this research: to me, to the researchers, and to any third parties involved ?

Taking part in this study may not directly benefit you personally. However, your participation may help researchers better understand HRV in female athletes. This may contribute to future improvements in female physiology in sport, exercise and health. Your data will not be shared with industry partners for commercial purposes.

10. What are the risks of taking part in this research study?

This is a low-risk study. The main inconvenience is the time needed to complete the questionnaire and, if you choose, to donate your existing tracking data. All data is collected in an anonymised format and you will not be identifiable.

11. How will I find out what happens with this research study?

The findings from this study may be presented at scientific conferences and published in academic journals. No information that could identify you will be included in any presentation, publication, or report. You can contact the research team directly at the provided email addresses for information on results or publications.

12. What information about me will be used in this research study?

This study is completely anonymous and no personal identifiable data is collected. Information collected includes:

- age range
- physical activity level
- menstrual cycle information (hormonal contraceptive use, menstruation, ovulation, menstrual symptoms and/or pregnancy)
- HRV data
- Temperature data (if your device supports this feature)

The study is designed so that identifiers such as your name, address, or personal contact details are not collected or included in the research dataset.

13. How will my data be used?

Responses will be combined with data from other participants and analysed to better understand HRV patterns in females. We recognize that information related to menstrual cycles and hormonal contraceptive may be considered sensitive, but all responses are anonymous, and no identifiable information is collected that can identify you after you submit your responses. Results may be shared through academic publications or presentations, but your identity will never be revealed.

At the end of the study, anonymised research data will be securely retained/archived by UCD for future research and verification purposes in line with UCD policy and research data management requirements, for a period of ten years.

14. Who will have access to my personal data? What will happen to my personal data?

The research team at UCD will only have access to the data collected for the purposes of this study. As this study is designed to be anonymous, the research team will not collect personal identifiers. Data will be handled confidentially and used only for the purposes described in this leaflet.

Access to the study data will be limited to authorised members of the research team.

15. (if applicable) Details of any transfers of personal data to third country (ie outside the European Union) or international organisations

No personal data will be transferred outside the European Economic Area (EEA) as part of this study.

16. How will my personal data be protected? Will it be kept confidential ?

The study is designed to minimise the collection of personal data. Data collected for research purposes will be stored securely on password-protected and access-controlled systems. Only authorised members of the research team will have access to the data. **The research team will not be able to identify participants** from the research dataset.

17. How long will my data be retained by this project ?

The anonymised data will be retained securely for 10 years after the end of the study (December 2030).

18. What is the lawful basis to use my personal data ?

This study is designed to collect anonymous data. No information that directly identifies you (such as your name, email address, or contact details) will be collected as part of the research dataset. Because the data are anonymous, data protection law such as the General Data Protection Regulation (GDPR) may not apply to the research dataset. However, you will still be required to provide consent before proceeding.

19. What are my rights ?

- If consent is used as legal basis, include the right to withdraw consent

Because this study is designed to be anonymous, it may not be possible to identify your data after submission in order to correct, retrieve, or delete it.

20. Contact details of Principal Investigator, UCD's Data Protection Officer (DPO) and right to lodge a complaint with the supervisory authority (Data Protection Commission)

Principal Investigator

Dr Sinéad Holden

School of Public Health, Physiotherapy and Sports Science

University College Dublin

Email: sinead.holden@ucd.ie

UCD Data Protection Officer

Email: gdpr@ucd.ie