INFORMED CONSENT FORM

Project Title: Sex differences in the minimum effective dosage of exercise for exerkine release

Primary Contact: Peter Higgins, PhD Candidate

Principal Investigator: Dr Paul Ansdell

Please read each statement carefully and initial the box next to each item to indicate your agreement.

General Consent

I have carefully read and understood the Participant Information Sheet.	☐
I have had an opportunity to ask questions and discuss this study and I have received satisfactory answers.	☐
I understand I am free to withdraw from the study at any time, without having to give a reason for withdrawing, and without prejudice.	☐
I understand that if I withdraw from the study, I may also request that any biological samples I have provided that have not yet been processed or analysed are destroyed. I understand that it may not be possible to withdraw data or samples that have already been anonymised, processed, or analysed at the point of my withdrawal.	☐

Biological Samples

I agree to have venous blood (plasma) taken via a cannula inserted into a vein in my arm and used to analyse for steroid hormones, and untargeted metabolomics.	☐
I agree to have capillary blood taken via earlobe-prick sampling and used to analyse for blood glucose, blood lactate, and haemoglobin.	☐
I agree to have saliva collected using the passive drool method and used to analyse for untargeted metabolomics.	☐
I agree to have urine collected and used to analyse for hydration status and untargeted metabolomics.	☐
I agree to have interstitial fluid collected from my forearm using a microneedle device (needle length 0.45 mm) with gentle suction, and used to analyse for untargeted metabolomics.	☐
I agree to the self-collection of stool samples at home and for them to be used for gut microbiome analysis, including DNA extraction and metagenomic sequencing. I understand that while this analysis targets microbial DNA, some human genetic material may be incidentally captured and will be removed during data processing.	☐

Sample Storage, Transfer, and Future Use

I understand that my biological samples will be stored at −80°C at Northumbria University and may be stored for up to three-years following completion of the study, after which they will be disposed of in accordance with institutional policy.	☐
I understand that my stool samples will be transferred to SeqBiome Ltd (Fermoy, Ireland) for metagenomic sequencing, and that samples for untargeted metabolomics analysis will be conducted at Northumbria University or transferred to King's College, London. I understand that these organisations will process my samples in accordance with their data protection and quality assurance procedures.	☐

I consent to my anonymised biological samples being used for future ethically approved research beyond the current study aims. *(If you do not initial this box, your samples will be destroyed upon completion of the analyses described in this study.)* ☐

Data and Publication

I understand that my data will be anonymised and stored securely in accordance with the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018. ☐

I am happy for the investigators to publish my experimental data in an anonymised fashion, with no identifiable information alongside it. ☐

Consent to Participate

I agree to take part in this study. ☐

Signatures

Signature of participant

Sign here (by hand, or draw/insert using your PDF viewer)

Date: _____

Name in block letters: _____

Signature of researcher

Sign here (by hand, or draw/insert using your PDF viewer)

Date: _____

Name in block letters: _____

Sex differences in the minimum effective dosage of exercise for exerkine release

Screening Questionnaire

The questionnaire will take you approximately 5 minutes to complete. The questionnaire consists of tick boxes or one-sentence answers. If you would prefer not to answer certain questions, please leave them blank. You are allowed to take the questionnaire away with you to allow you to answer the questions in private. If you need any help answering the questions, please do not hesitate to contact the lead researcher. Please see contact details at the end of the questionnaire.

Date of Birth (dd/mm/yy):

[ ] / [ ] / [ ]

Home postcode:

[ ]

Sex assigned at birth:

- [ ] Female
- [ ] Male

Ethnicity:

- [ ] a. White
- [ ] b. Black, Black British, Caribbean or African
- [ ] c. Asian or Asian British
- [ ] d. Mixed or multiple ethnic groups
- [ ] e. Prefer not to say
- [ ] f. Other ethnic group

1. How often do you take part in <u>structured aerobic physical activity?</u>

For example: Jogging, team sports, spinning, cycling etc.

Please tick one:

- [ ] a. Once a week
- [ ] b. Twice a week
- [ ] c. Three times a week
- [ ] d. Four times a week
- [ ] e. More than 5 times a week
- [ ] f. Never

How many hours in total per week?

[ ]

2. How often do you take part in <u>any other physical activity?</u>

For example: resistance training etc.

Please tick one:

- [ ] a. Once a week
- [ ] b. Twice a week
- [ ] c. Three times a week
- [ ] d. Four times a week
- [ ] e. More than 5 times a week
- [ ] f. Never

How many hours in total per week?

[ ]

3. How long have you been maintaining this <u>level of aerobic activity?</u>

Please tick one:

- [ ] a. 1-3 months
- [ ] b. 3-6 months
- [ ] c. 6-12 months
- [ ] d. Less than 1 month

4. Do you have any medical conditions?

For example: Arthritis, Myositis, Fibromyalgia, Myopathy, Diabetes Mellitus, or Hypothyroidism

☐ Yes ☐ No

If yes, please elaborate:

5. Are you currently taking any medication?

☐ Yes ☐ No

If yes, please elaborate:

6. Are you currently taking any nutritional supplements or vitamins?

For example: Protein supplements or vitamin tablets

☐ Yes ☐ No

If yes, please elaborate:

7. Do you have any dietary restrictions or allergies?

For example: vegan diet or gluten allergy

☐ Yes ☐ No

If yes, please elaborate:

8. Do you currently have any musculoskeletal or tendon injury?

For example: Sore muscles, broken bones or sore tendons

☐ Yes ☐ No

If yes, please describe information regarding the type of injury, injury location, and when it occurred (dd/mm/yy):

9. Do you have any metal implants anywhere in your body?

☐ Yes ☐ No

10. Do you drink alcohol?

☐ Yes ☐ No

If YES, how many units a week?

(4% pint lager / 13% 175ml wine = 2.5 units)

11. Smoking history

Do you currently smoke?

☐ Yes ☐ No

If YES, approximately how many per day?

Previous smoker?

☐ Yes ☐ No

If YES, how long since stopped? ☐

12. Do you take an inhaler?

☐ Yes ☐ No

If YES, which inhaler(s)? ☐

If YES, have you got it with you today?

☐ Yes ☐ No

<u>If a female participant please answer questions 13-25</u>

13. Have you <u>ever</u> severely controlled your diet to achieve a dramatic change in weight?

☐ Yes ☐ No

14. Do you have any children?

☐ Yes ☐ No

If no please go to question 16

a. Please list the date/s you had your child/children (dd/mm/yy):

1) ☐ / ☐ / ☐

2) ☐ / ☐ / ☐

3) ☐ / ☐ / ☐

4) ☐ / ☐ / ☐

15. Have you breast fed in the last year?

☐ Yes ☐ No

16. At what age did you start your period?

☐

years old

17. On average how long does your menstrual cycle last (how many days between a period)?

☐

days

18. On average how long does your period last?

☐

days

19. Have you had a regular period for the last six months (one period at least every month and no spotting in-between periods)?

☐ Yes ☐ No

What was the date of your last period (dd/mm/yyyy)?

Please give the first day of bleeding of your most recent period. This helps us schedule your visits around your cycle.

☐ / ☐ / ☐

20. Have your periods stopped?

☐ Yes ☐ No

☐ Yes ☐ No

22. Have you ever had your ovary / ovaries removed?

☐ Yes ☐ No

23. Have you ever taken the oral contraceptive pill?

☐ Yes ☐ No

If no please go to question 24

a. What type of pill did / do you take (name and dose of oestrogen and progesterone)?

Dose values can be found on the medication box. If you are unsure, please bring your medication with you.

b. When did you start taking the pill (mm/yy)?

c. If you have, when did you stop taking the pill (mm/yy)?

24. Have you ever used any other form of hormone-based birth control (injection, vaginal ring, etc.)?

☐ Yes ☐ No

If no please go to question 25

a. What type of hormone-based birth control did / do you take (name and dose of oestrogen and progesterone)?

Dose values can be found on the medication box. If you are unsure, please bring your medication with you.

b. When did you start using the contraception (mm/yy)?

c. If you have, when did you stop using the contraception (mm/yy)?

25. Have you ever used hormone replacement therapy?

☐ Yes ☐ No

Thank you for your time whilst completing the questionnaire. All information will remain strictly confidential.

Contact details:

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Dr Paul Ansdell, Supervisor
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Once complete, save this form and email it back to peter.r.higgins@northumbria.ac.uk.

Next steps: we'll be in touch to book you in for your next available session.