



UCD Institute for Sport & Health



PARTICIPANT INFORMATION LEAFLET

Study Title — Investigating the Genomic Basis of Fitness and Health

Principal Investigator — Prof. Giuseppe De Vito and Dr. Sean Ennis

Sponsor — Genomics Medicine Ireland Ltd.

You are being invited to take part in a research study. **Participation involves a one-off appointment.** Please read the following information carefully. If you have any questions or if you would like more information about the research study, please ask the research team. **Participation in all research is entirely voluntary.**

Because of the health-related nature of the personal information that you have provided to us, the lawful basis on which we process your data is “consent”.

1. WHO IS ORGANISING AND FUNDING THE RESEARCH AT THE CLINIC?

This Study is being organised by lead researchers at University College Dublin (UCD) and Genomics Medicine Ireland (“**GMI**”).

The study is funded by GMI. Founded in 2015, GMI, a commercial life sciences company, is carrying out this research. They undertake genomic research together with hospitals, primary care centres, universities and commercial partners. These include, but are not limited to, companies who develop new diagnostic tests, identify new risk factors or drug targets, and develop, test and market new drugs. Through the potential collaboration with these companies, they hope the information gained in this study will lead to the development of new tests and treatments.

Additional clinics may also participate in this research however each clinic will maintain and govern its own study data.

2. WHAT IS THE RESEARCH STUDY?

We are investigating the role our genetic material, fitness levels and lifestyle choices have on our health.

Our genomes (genetic material) are like instruction manuals containing the information needed to make, run and repair each person. From one person to the next, there are

many differences in our genomes. Some of these differences have no effect on how we function, while others can contribute to good health or disease. Why is this? What triggers the onset of a disease? Is it something to do with the environment or lifestyle? Or is it other genes? These are the types of questions that we hope to try to answer by studying biological samples together with health and lifestyle information.

This study aims to analyse the entire genetic code to identify specific changes in our genetic and biological material (contained in our blood) which may help us to identify (1) DNA changes associated with good health, fitness and protection against disease and (2) DNA changes that either cause or contribute to a wide-range of diseases. We also aim to evaluate the influence our fitness levels and lifestyle choices have on our health status.

It is hoped that the information gained from this study will improve our understanding of genetic factors that contribute to living a long and healthy life and the accompanying lifestyle choices that further promote wellbeing.

3. WHAT WILL THE RESEARCHERS LOOK AT?

Blood samples contain our genetic material. This study will examine substances in your blood called DNA, RNA, proteins and metabolites. We refer to these as biological materials or biological samples. We will be using techniques such as whole genome sequencing (a process that reads every letter of our DNA [or genetic instructions]).

By studying the health, lifestyle, genetic and other biological material information of thousands of people with a health condition and comparing it to information from thousands of people without that condition, we can identify specific patterns that help us to better understand wellness and the condition. We need to look at these samples from a large number of people so that we can study the differences between them, and how they relate to health.

This approach will provide a more detailed view of how and why a condition develops.

4. CAN I TAKE PART IN THE STUDY?

You can take part because you are over the age of 18 years and can make your own decision about taking part in this study.

5. WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?

You will be given as much time as necessary to think this over and to ask questions.

If you agree to participate in this study, you will be asked to do the following:

- give consent to take part in this study;
- complete a lifestyle questionnaire;
- complete a short fitness test called a PWC-170 using a stationary bike ergometer and a simple muscle strength test;

- allow quantitative measurements of external and visceral body fat percentage, bone mineral density and muscle percentage to be taken with a total body DEXA scanner (Dual Energy X-ray Absorptiometry), if appropriate;
- allow the research personnel to take the following measurements - height, weight, hip and waist circumference, blood sugar and blood pressure levels;
- give up to 1.4 tablespoons (~20ml) of blood.

6. HOW IS THE INFORMATION I PROVIDE PROTECTED?

Personal identifiers, such as your name or date of birth, are never used to label your samples or clinical information. All samples and study information are assigned random study ID numbers at the clinic in a process called pseudonymisation. This process is intended to mask your identity.

Protecting your privacy is extremely important to GMI and the research team at the clinic. All technical and legal measures that are available to GMI will be used to help ensure that each participant's identity remains confidential. In particular, highly secure IT industry standard methods are used to protect the database from accidental access or intentional abuse. There is a remote risk that a connection to your identity could be made. However, researchers accessing the data will enter a legal agreement with GMI not to make any attempt to identify participants.

If required, in very special cases (for instance withdrawal from the study), this process can be partly reversed using two decryption keys; one held by GMI and the other by the study research team. This process cannot be fully reversed without the research team. Your random study number can only be linked to your name by the research team. This means that your identity has been doubly secured.

7. WHAT WILL HAPPEN TO MY BIOLOGICAL SAMPLES?

Your biological samples will be processed in certified genetic laboratories. GMI has a clinical genetics laboratory in Dublin, which will be used as one of the main laboratories to process your biological samples and data in accordance with certified standards. We will also be using certified laboratories that may be located both inside and outside the European Union to process your biological samples. Any data generated will be protected as required by Irish and EU data protection laws and GDPR. This may involve the use of data transfer agreements in the form approved by the European Commission under data protection law, protecting personal data transferred outside the EEA (for example, the standard contractual clauses). For more information on this and individuals' rights please visit the privacy statement on GMI's website (<https://genomicsmed.ie/privacy-statement/>).

During the study, your biological samples and lifestyle information will be safely stored at the clinic before being transferred to GMI. The biological samples will then be stored at GMI (located in Dublin). Personal identifiers, such as name or date of birth, are never used to label your samples.

Ten years after the study start date, your biological samples will be destroyed unless the research team applies to and is given approval by the relevant ethics board to continue with the research.

The information that links your name with your study number is held securely in the clinic. These documents will be destroyed 20 years after the research study begins. This time frame may change depending on regulatory, ethical or legal requirements.

8. WHAT WILL HAPPEN TO MY DATA?

Your health, lifestyle and biological information will be studied together with that of other individuals to look for patterns in the grouped data. The research data will also be used in other health-related analyses and as a comparison in other diseases to help understand normal biological changes that may be associated with health.

Data analyses will be conducted only by GMI researchers, the research team and/or authorised third parties such as academic research groups, pharmaceutical/ biotechnology research groups and commercial companies, in order to increase the chance of important discoveries.

In rare cases, the study may include individual analyses of a participant's data and biological material if it is believed this could lead to important study findings. However, your data and the results from any analysis will not contain any information that traditionally would be used to identify you.

The health and lifestyle data and information that comes from the biological materials may be kept forever in a secure GMI database to support continuing scientific research. This is important for research because as changes and advances emerge over time, the data we collect may gain new significance. More information on our data privacy policy is available on the GMI website at <https://genomicsmed.ie/privacy-statement/>.

The findings from this research may appear in published scientific articles. Your name, date of birth, address will never be included in these publications. In general, these articles relate to group studies. In exceptional circumstances, individual analyses may be published in a manner that aims to protect your identity.

You are entitled under data protection law to request a copy of all the personal data you provided as part of this study.

9. HOW LONG IS THE STUDY AND WILL THERE BE ANY FOLLOW UP?

This is on average a 5-year study. Participation in this research is by once-off appointment. If any future research opportunities arise, you can decide if you would like to be contacted by the research team by ticking 'yes' or 'no' on the consent form.

10. WHAT ARE THE BENEFITS OF PARTICIPATING?

You will not receive any feedback relating to your own personal genomic results.

However, you will be informed of your health measurements (height, weight, hip and waist circumference, blood sugar and blood pressure levels), aerobic fitness, muscle strength and DEXA scan results obtained during your appointment and these will be discussed in detail with you. If you wish, you can then make a follow-up appointment as per your usual arrangements with your General Practitioner to discuss your results.

Information obtained from the study will identify genomic changes in the Irish population that contribute to healthy ageing, fitness and wellness. It may also help us to better understand multiple different health conditions and to improve diagnoses and treatments in the future.

You will not benefit financially in any way should this research lead to the development of a new treatment or medical tests. You should be aware that GMI and/or third-parties may benefit financially from information gained from this study.

11. ARE THERE ANY RISKS INVOLVED IN PARTICIPATING?

You may experience discomfort and superficial bruising at the site where the blood is taken. You may also feel faint, experience dizziness, swelling and possibly infection at the site. These are the normal risks associated with giving a blood sample. Care will be taken to avoid such complications. Bloods will only be taken by trained staff such as a nurse or research team members who are experienced in taking blood. If you have questions or concerns, speak to the research nurse or the research team.

Your research team are insured with medical professional indemnity cover. Your statutory rights are not affected by signing this consent form.

12. WHAT HAPPENS IF I DO NOT AGREE TO PARTICIPATE?

Participation in this study is entirely voluntary.

13. CAN I WITHDRAW FROM THE STUDY?

Yes. You can withdraw from this study by telling the research nurse or member of the research team who will notify GMI. The contact details are included at the end of this document if you wish to withdraw from the study. You do not have to give any reason. Once the study records linking your name with your study number have been destroyed at the

end of the study, as outlined in section 7, it will not be possible to withdraw as the clinic and GMI will not be able to tell which biological samples and data belongs to which participant.

If you decide to withdraw, and your data has not yet been processed GMI will:

- Promptly destroy your biological samples without further use.
- Delete your lifestyle and biological data

If you decide to withdraw, and your data has been processed:

- GMI will promptly destroy your biological samples without further use
- No further contact will be made with you regarding this study
- Your data cannot be withdrawn from research already in progress or completed, or from published results and findings.
- Your health, lifestyle and biological data generated as part of this study will be retained forever for scientific research purposes, in accordance with EU data protection laws and GDPR (see our privacy statement www.genomicsmed.ie/privacy-statement/). This data will only be processed for the purposes outlined in this leaflet. It will not contain any information that traditionally would be used to identify you (such as name or date of birth).

14. ARE THE PRINCIPAL INVESTIGATORS BEING PAID FOR THIS STUDY?

The Principal Investigators are not being paid directly for this study. In funding the study, GMI cover the cost of staff and resources required to undertake this research study.

15. WHO CONTROLS ACCESS TO MY DATA AND BIOLOGICAL SAMPLES?

- The research team will collect and be responsible for your **study data and biological materials** before they are transferred to GMI.
- The research team holds **research study records** for instance consent forms and documentation generated from this study. GMI and the Principal Investigator jointly control access to these records.
- Access to all **data and biological samples** provided to or generated by GMI as part of this research study will be controlled by GMI.

16. WHO CAN ACCESS MY DATA AND BIOLOGICAL SAMPLES?

Once transferred to GMI, access to your data and samples is tightly controlled as follows:

Data in the GMI database

a. Storage of your Data:

- Your lifestyle and biological data is stored securely in a GMI database. This database does not contain any information that traditionally would be used to identify you, for example, name or birth date.
- GMI owns the database and it will be held in a secure place with a high level of access control.

b. Access to your Data held by GMI:

- GMI will give a copy of your health and lifestyle data to the research team.
- GMI will allow approved pharmaceutical/biotechnology companies and research groups to have strictly controlled access to your lifestyle and biological data for the research purposes outlined in section 8.
- Approved users may be located outside the EU.
- All access will be in line with Irish and EU data protection laws (GDPR).

Biological samples

- GMI does not provide access to your biological materials to any third-parties except for small amounts of the biological sample that may be sent to external certified or approved laboratories for processing (as outlined in section 7), to generate the data required as part of this research study.

The following groups (who will be required to obey Irish and EU data protection law and process your data in accordance with this consent) may also be given access to the data, records, samples and/or GMI database: (1) the Ethics Committee and Regulatory Authorities (2) GMI personnel who conduct and monitor the study; (3) any party to whom we are under a legal duty to disclose your data; and (4) any company who may later acquire GMI.

17. WILL I GET PAID FOR PARTICIPATION?

No payments, compensation or other expenses will be made to individuals taking part in this study.

18. HAS THIS STUDY BEEN REVIEWED BY AN ETHICS COMMITTEE?

The University College Dublin Research Ethics Committee has reviewed and approved this study. If the research questions and/or the way the data is used changes in any significant way, ethical approval will be required, and if you agree, you may be contacted and asked for further consent.

19. CONTACT DETAILS

Please contact: the GenoFit clinic for further information or for withdrawing from this study.

Phone number: [Insert phone number here]

Email address: [Insert email address here]

Postal Address: [Insert postal address here]

In the event that you wish to make a complaint about how your personal data is being processed by GMI we encourage you to contact GMI's Data Protection Officer first at dataprivacy@genomicsmed.ie

If you feel you haven't received a timely or satisfactory response from GMI to your question or complaint, please contact the Data Protection Supervisory Authority (www.dataprivacy.ie).

This participant information leaflet is yours to keep. If you agree to participate in this research, you will be given a copy of the signed consent form for your records.