Participant Information Sheet (PIS)
Assessing the Metabolic Effect of Sustainable Proteins (AMES-PRO)

You are being invited to take part in a research study. Before you decide whether you would like to participate, it is important for you to understand why the research is being performed and what it will involve. Please take time to read the following information carefully and discuss it with your friends, relatives, and your GP if you wish. If there is anything that is not clear or if you would like more information, you can contact the study researchers (Dr Jennifer Pugh, e-mail: jennifer.pugh3@nhs.net or Dr Aygul Dagbasi, e-mail: aygul.dagbasi@nhs.net). Take time to decide whether you wish to take part. If you do decide to take part, please let us know beforehand if you have been involved in any other study during the last 12 weeks. You are free to withdraw at any time without giving a reason. Thank you for reading this.

What is the purpose of the study?

Red meat consumption has increased around the world. This growing demand may not be met by the current agricultural practices. Meat production is a major source of carbon dioxide emissions, which contribute to global warming. It is highly intensive in its water and land use. Furthermore, environmental damage including runoff and habitat degradation from farming practices raises concern about their long-term sustainability.

In parallel, a growing awareness of potential health risks linked to high red and processed meat consumption has prompted many individuals to seek alternative sources of protein. As a result, there has been a shift towards more sustainable and health-conscious protein options, such as fermented products and plant-based proteins. Examples include mycoprotein (known as Quorn), and soy protein. Moreover, sustainable, plant-based proteins may provide other health benefits. Evidence suggests that the enhanced fibre content or specific food structures of some plant-based proteins may reduce cholesterol and improve blood sugar control, potentially improving long-term health outcomes.

However, it is unclear how the human body digests these new protein sources and how this impacts subsequent metabolic responses. The aim of the current study is to understand how meat alternatives, both fermented and non-fermented, are digested and metabolised, compared with red meat, in humans. We will use a fermented vegetable-based product called Matr and its unfermented alternative. This product is certified and sold for human consumption, predominantly in Denmark. For further information on how Matr is made, what it contains and its nutritional composition, please visit to https://matrfoods.com/

To understand the effect of these products on human health, we will give these products to our volunteers and then collect blood and stool samples, questionnaires about appetite, breath measurements and an assessment of body composition. This will be repeated three times with different products. Detailed description of the study can be found in the "**What will happen to me if I take part?"** section. The results from this study will help us to understand how sustainable proteins impact human metabolism which can help sustain the protein requirements of a growing global population.

Why have I been chosen to participate?
You have been chosen to participate because you are a healthy adult who is eligible to participate in this study, per our eligibility criteria below. Your participation can help us understand the effect of sustainable proteins on human health.

Who is eligible to participate in the study?

You are <u>eligible</u> to participate if you meet the following criteria:

- Body mass index (BMI) of 18.5-29.9 kg/m^2
- Individuals aged between 18-65 years (inclusive)

You are <u>not eligible</u> to participate if you have any of the following:

- Weight change of >3 kg in last 3 months
- HbA1c (an indicator of blood sugar control) greater than 41 mmol/mol (8.5%)
- Bowel reconstruction surgery
- Dietary requirements (e.g. vegan or vegetarian)
- Food allergies or intolerances
- Blood donation in the last three months
- Current smokers
- Substance abuse
- Excess alcohol intake (>14 units per week)
- Pregnancy or breastfeeding
- Cardiovascular disease
- Cancer
- Kidney failure
- Participation in another research study in the past 12 weeks
- Diagnosed gastrointestinal conditions
- Use of antibiotics in the past three months
- Use of anti-inflammatory drugs or steroids or thyroid hormones.
- New medication in the past three months
- Any other reason in the opinion of the investigator (e.g. likely to find it difficult to comply with the study protocol)

Do I have to participate in this research study?
It is entirely up to you to decide whether you want to participate in this research study. If you do decide to participate, you will be given an informed consent form to sign and keep for your records. You will also be given a copy of this participant information sheet to keep. With your consent, we will inform your GP of your participation in this study. You can withdraw from this study whenever you wish to do so, and you do not need to give any reason for your decision. Your participant status and standard of care will not be affected by your withdrawal from this study.

What will happen to me if I take part?

Screening Visit (Up to 1 hour):
If you are eligible and decide to participate in this study, you will be invited to attend the NIHR Imperial Clinical Research Facility at Hammersmith Hospital (W12 0HS) for a screening visit. You will be able to ask us any further questions you might have about the study. You will also receive a hard copy of this information sheet. After all your questions have been answered and if you are still willing to participate in the study, you will be asked to sign a consent form.

You will then go through a health screening for the study where you will be interviewed and examined by one member of the research team. You will have a blood test (to ensure that you are not anaemic or diabetic) and height, weight, and blood pressure measurements will be taken. All women of childbearing age will have a pregnancy test. During this visit, you will complete a brief study eligibility questionnaire in which you will need to complete information about any medication you are taking, past medical and family history of any conditions and GP details. The results of these measurements (weight, height, blood pressure and pregnancy test) will be recorded in this questionnaire.

You will be informed (by phone or e-mail) by a member of the research team whether the blood test, blood pressure and body weight measurements results make you eligible to participate in the study. Your GP will receive a copy of your blood test results.

Online dietary recall tool
Libro is an easy-to-use, self-reporting online tool that records what a person eats and drinks. It can be used on a smartphone via an application and you will be provided with login details. You will not be required to input your email address or name. You will record what you have been eating and drinking during the 4 days before each study visit.

Dietary Interventions

If you are eligible and would like to participate in the study, you will be invited to the NIHR Imperial Clinical Research Facility for three separate visits. During these visits, you will be given three different diets. These will either contain A: Fungi-based fermented sustainable protein source product called Matr, B: Matr's unfermented alternative or C: Beef. Matr is certified and sold for human consumption, predominantly in Denmark. Outside of your study visits, you may continue to follow your usual diet throughout the duration of the study.

There is a minimum of 1-week gap between Study Visit 1, 2 and 3. The whole study will take around 5 weeks. A Study Outline Diagram is shown below.

Study Outline

Study Visits 1-3

Each visit will follow the same protocol, listed below.

Four days before you arrive for your visit, we will ask you to start recording your dietary intake using the Libro application. The day before you are due to come for your visit, we will also ask you to collect a stool sample at home using the kit provided by the team and bring this to your visit the next day. We will also ask you to avoid alcohol and strenuous exercise the day before your visit.

Day 1: You will come to the unit around 3 pm. Women of childbearing age will be asked to provide a urine sample. You will be served an evening meal around 5 pm and asked to consume this in 15 minutes. You will be served another snack at 8 pm and asked to consume this in 15 minutes.

Each visit will last around **25 hours.** You cannot leave the facility during this time. You will stay overnight in a private ensuite room with shower facilities (towels provided). Please bring anything you require to be comfortable and have a good night's sleep. This may include:

- Pyjamas
- An eye mask and ear plugs
- Toiletries (including shower gel/shampoo, should you wish to shower)

- A change of clothes
- Entertainment (e.g. laptop, chargers for devices, book, headphones)

Day 2: At approximately 8:30 am, your weight and blood pressure will be measured and you will be asked to collect your urine throughout the day in a large container. Following this, a member of the research team will place a cannula (a small, flexible plastic tube) for testing in your arm that will stay in place during the study visit, which will allow us to take blood without causing you further discomfort.

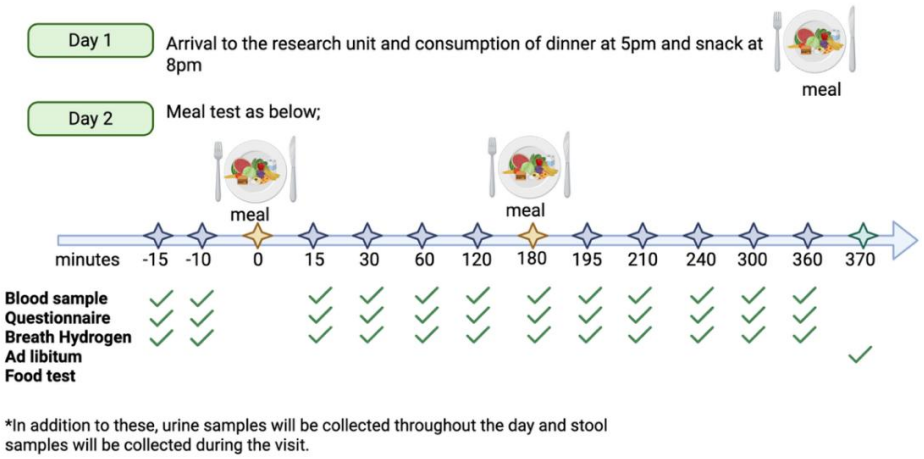
Two fasted blood samples (10 ml each) will be collected through this cannula and you will be given a questionnaire on your appetite and a breath test to complete. You will be given breakfast around 9am. After breakfast, at regular intervals, you will have a blood sample taken (10 ml of blood, duration: 5 minutes) and complete an appetite questionnaire (duration: 2 minutes) and a breath test (duration: 1 minute). Five measurements will be taken between breakfast and lunch. Lunch will be served around midday, and five further measurement will be taken after lunch.

In total, 120 ml (8 tablespoons) of blood will be taken, and 12 questionnaires and breath tests will be completed during each study visit (for further clarification please refer to the sample collection outline below).

A final meal will be served around 3pm. This is called an ad-libitum food test and will help us to measure your food intake. You will be asked to consume the bowl of pasta until you are comfortably full. After this meal, the cannula will be removed, and you will be free to leave.

Please note: you will not be allowed to eat or drink anything else during the visit. We will encourage you to eat everything on your plate to keep portions as consistent as possible between your different visits and between different participants. **We may withdraw you from the study if you cannot finish most (85% or more) of what we serve you.**

Sample collection outline:



*In addition to these, urine samples will be collected throughout the day and stool samples will be collected during the visit.

What are the potential advantages if I decide to participate?
The study will not directly benefit you. However, we hope that the information we will gather through your participation will help us identify how sustainable proteins are digested in the human body which could assist with the formulation of sustainable proteins in the future.

What are the potential risks and/or disadvantages if I decide to participate?
In the event we discover something about your health that you were not aware of, such as abnormal kidney test result or possible type 2 diabetes, we will inform you of this immediately. If you require more urgent assessments, we will arrange these for you immediately within the hospital. In addition, your GP will be informed of the blood test results that were taken at the consent and screening visit.

Procedures such as recording your weight, height, appetite questionnaires and breath tests do not pose any risks to your health. Blood sampling may produce mild discomfort when the needle is inserted, possible bruising and localised infection. To reduce any of these risks, blood sampling will only be performed by appropriately trained doctors, nurses, or members of research team under aseptic conditions.

All meals provided by the study team are safe for human consumption and do not pose any risk to human health.

Will I be reimbursed for my travel expenses and time?
You will receive £225 for completing all three study visits (£75 for each of study visits). In addition, you will receive compensation for travel expenses provided you show us proof of travel (e.g., bus/train ticket). Payments will be made via bank transfer at the end of the study. **Payment forms are submitted by the study team**

to the Imperial Finance Department, once submitted, payments can take up to 6 weeks to be processed.

What happens when the research study stops?
Once the study has finished, the data that was gathered will be analysed by members of the research team. Then, the results can be made available to you upon request. If you have any problems immediately following the study, then you should contact one of the research team members on the emails provided.

What happens with the samples I have provided?
During the study, you will provide blood, urine and stool samples. These samples will be allocated a study ID number and stored without any personally identifiable information in a laboratory freezer belonging to the Section of Nutrition. This freezer is found within a locked room, accessible to those with a pre-approved access via Imperial identity card. Only delegated members of the study team will have access to your samples. Once samples have been analysed, they will be disposed of in line with the hazardous waste policy and disposal policies at Imperial.

What if new information becomes available?
During a research study, new information sometimes becomes available about the intervention that is being studied. If this happens, the research team member will tell you about it and discuss with you whether you want to continue in the study. If you decide to continue with the study, you will be asked to sign an updated informed consent form. Upon receiving new information the research team member might also consider whether it would be in your best interests to withdraw you from the study.

What will happen if I no longer wish to continue participating in this research study?
You can withdraw from the study any time you wish so, without giving any reason. You can contact either of the researchers (Jennifer or Aygul), to withdraw from the study. Your participant status will not be affected. No further samples (blood, breath, urine, and faeces) and data will be collected if you decide to withdraw. Any samples (blood, breath and questionnaires) and personal data that are identified as belonging to you that have already been collected will be retained and used in the data analysis and, if you gave consent, for future ethically approved studies. In the unlikely event that you lose capacity to consent during the study you will be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected, or any other research procedures carried out.

What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College London is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during this study then you should immediately inform the Investigator (Prof Gary Frost, e-mail: g.frost@imperial.ac.uk). The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team.

What could I do if I have complaints or concerns?
If you wish to complain or have any concerns regarding the ways you have been treated during this research study, you should contact the Principal Investigator of this study, Professor Gary Frost by phone 0207594739 or by e-mail g.frost@imperial.ac.uk.

How will we use information about you?
Imperial College London (Sponsor ID: 179948) is the sponsor for this study and will act as the Data Controller for this study. Being a Data Controller means that we are responsible for looking after your information and using it appropriately plus are responsible for explaining this to you.

Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

The study data will then be fully anonymised and securely archived or destroyed.

The study is expected to finish in September 2026.

For more information / confirmation regarding the end date please contact the study team, see '**WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED'** for contact information.

We will need to use information from you for this research project.
This information will include your:

- NHS number
- Name
- Contact details

People within the College and study team (see section sharing your information with others) will use this information to do the research or to check your records to make sure that research is being done properly and the information held (such as contact details) is accurate. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

As a university we use personally identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we must ensure that it is in the public interest when we use personally identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

• Imperial College London - "performance of a task carried out in the public interest"); Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), Imperial College London relies on "scientific or historical research purposes or statistical purposes.

International Transfers:
There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA)).

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Organisations that will analyse the data
- Organisation that provided the food products for the trial

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following;

- The countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- We use specific contracts which stipulates that personal data must maintain the same level of protection when outside the UK as it has within the UK. For further details visit the Information Commissioner's Office (ICO) website - www.ico.org.uk
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- We have procedures in place to deal with any suspected personal data breach. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website - Personal data breaches: a guide | ICO

Sharing your information with others

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

- Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

  Research Collaborators / Partners in the study

- Matr Foods – all anonymised data will be shared since they are our study collaborators, and they are providing the meals consumed in the study
- Glasgow University – only blood and urine samples will be sent for analysis that cannot be conducted at Imperial College London.

Potential use of study data for future research

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have because some research using your data may have already taken place and this cannot be undone. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you if this could affect the wider study or the accuracy of the data collected.

Where can you find out more about how your information is used

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team members
- by sending an email to imperial.dpo@nhs.net
- by ringing us on 020 3311 7344

Complaint

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to g.frost@imperial.ac.uk or by ringing us on 020 7594 0959.Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

What will happen to the results of the research study?
The results of this study will be published in relevant nutrition peer-reviewed journal articles or presented at scientific conferences, internal conferences/group meetings. Your confidentiality will always be ensured, and you will not be identified in any publication or scientific conference. Each participant will receive an email with the summary of the study results.

Who is organising and funding the research?
The study is being organised and sponsored by Imperial College London and is part of a grant funded by Bezos Centre Imperial College London. The sponsors of this study will pay the Imperial College Clinical Research Facility for including you in this study.

Who has reviewed the study?
This study has been reviewed and given a favourable opinion by the Research Ethics Committee, REC reference 25/ES/0080

Contact for further information.
The Principal Investigator coordinating this study, Prof Gary Frost, can be reached during working hours by phone 0207 594 7239 or by e-mail: g.frost@imperial.ac.uk. At all other times, you can get in touch with the Hammersmith Hospital Switchboard at 020 8383 1000.

Thank you for reading this!
If you are interested in taking part in the study, please contact the study team to arrange a screening appointment.
A copy of this written information and signed Informed Consent form will be given to you.