Title of project:

- **BOLT Part A:** The effects of commercially available high protein drink on amino acid bioavailability in 18-45-year-old male and female participants.

- **BOLT Part B:** The effects of commercially available high protein drink on recovery from muscle fatiguing exercise in 18-45-year-old male and female participants.

NCT Number:

- **TBC**

Date:

- **01.2.25**

PARTICIPANT INFORMATION SHEET

Please take the time to review this document and ask any questions you may have about the study before volunteering to take part.

Section A: The Research Project

1. **Title of project: BOLT Part A:** The effects of commercially available high protein drink on amino acid bioavailability in 18-45-year-old male and female participants.

2. **Purpose of study**

Part A of the BOLT study will focus on characterising the total and essential amino acid concentrations for 4 hours following the consumption of a single serving of: 1) commercially available high-protein yoghurt drink, 2) a micellar casein drink, and 3) a flavoured water-based placebo drink. This is called a bioavailability study.

The results will provide novel insights into protein sources and may enable future application in products available to the consumer. Therefore, the main aim of this study is to compare changes in blood proteins (amino acids) following the consumption of a high protein yoghurt drink to a micellar casein drink and a flavoured water-based placebo drink.

This research study is being undertaken by Anglia Ruskin University, in Cambridge in collaboration with a nutrition company, Danone Global Research & Innovation Center, in the Netherlands.

3. **Who is the researcher?**

This project is led by Dr Ash Willmott with support from Dr Sanjoy Deb and the research team at the Cambridge Centre for Sport and Exercise Sciences at Anglia Ruskin University.

4. **Why have I been asked to participate?**

You are invited to participate in this research study based on your interest in the area and as a generally healthy adult. Before you decide whether to do so, it is important that you understand the research that is being undertaken and what your involvement will include. Please take the time to read the following information carefully and discuss it with others if you wish. Feel free to ask us anything that needs to be clarified or for any further information that will help make your decision. Please take your time to decide whether or not you wish to take part. Thank you for reading this.

There are a number of key inclusion criteria listed below; please check that all apply to you:

<u>Inclusion criteria</u>

- Age ≥ 18 and ≤ 45 years.
- Body Mass Index (BMI) ≥ 18.5 and ≤ 29.9 kg/m^2 (measured at the first assessment).
- Written informed consent (undertaken at the first assessment).
- Willingness and ability to comply with the protocol in the opinion of the investigator.
- Judged by the investigator to be in good health as assessed by a health screening questionnaire.
- Currently identifies as the same biological sex as at birth.

As with any study, there are also important exclusion criteria which will prevent you from being able to take part in this study – please check that none of these apply to you. Unfortunately if any criteria apply to you, you will be unable to participate in this research study.

Exclusion criteria:

- Any known ongoing medical condition that might interfere with absorption and digestion and/or gastrointestinal (GI) function (e.g. inflammatory bowel disease, gastroesophageal reflux disease, celiac disease, diaphragmatic hernia or diaphragmatic surgery, gastric ulcer, gastritis, gall bladder problems, pancreatitis, GI cancer, oesophageal and/or gastric surgery).
- Known musculoskeletal or soft tissue injury.
- Known cardiovascular disease, disease related to the immune system and/or the respiratory system.
- Known renal or hepatic failure or known thyroid dysfunction.
- Known Diabetes Mellitus type I or type II, insulin resistance or metabolic syndrome.
- Any ongoing cancer (except for basal cell carcinoma) and/ or cancer treatment.
- Known anaemia or low haemoglobin or low iron status.
- Any known bleeding disorder or reaction to withdrawal of blood samples.
- Use of oral and systemic use of prokinetics, laxatives, antidiarrheals, anticoagulants within 2 weeks prior to screening.
- Use of systemic antibiotics within 4 weeks prior to screening.
- Any known dietary allergies.
- Any known intolerances to ingredients of the study product, i.e. dairy, cow's milk allergies or lactose intolerance.
- Self-reported adherence to a strict dietary regime (e.g. vegetarian/ vegan/ paleo/ketogenic/intermittent fasting/ high protein diet (>1.6 g/kg body weight/day), or protein supplementation or a weight loss program, as confirmed via the screening process.
- Use of any nutritional supplements or additional protein supplements or nutritional support within 4 weeks prior to screening.
- Engage (on average) in more than 2 resistance exercise sessions and/or more than 4 exercise sessions in total weekly within 2 months before screening.
- Considered as endurance trained, competitive athletes or trained weightlifters, powerlifters or bodybuilders, in the opinion of the investigator.
- Known pregnancy and/or lactating,
- Current smoking or stopped smoking for <1 month prior to screening (except for incidental smoking of ≤3 cigarettes/cigars/pipes per week on average in the last month).
- Average alcohol use of >21 glasses* per week for men or >14 glasses per week for women (on average during the last 6 months) or drug/ medicine abuse in opinion of the investigator,
- Participation in any other clinical study with investigational or marketed products concomitantly or within 4 weeks before screening,
- Major medical or surgical event requiring hospitalization within the preceding 3 months and/or scheduled in the period of study participation relevant in the opinion of the investigator.

Note: *1 glass of alcohol is a standard serving per type of alcohol. According to the Centres for Disease Control and Prevention 1 drink is defined as 340 ml of 5% ABV beer, 142 ml of 12% ABV wine, 43 ml of 40% ABV distilled spirits or liquor.

5. **How many people will be asked to participate?**

Approximately 12 people will be invited to participate in this part of the study.

6. **Do I have to take part?**

Participation is completely voluntary, and you have the right to withdraw at any time without providing reason or judgment. To withdraw, please use the form at the bottom of the consent form provided or contact the Principal Investigator - Dr Ash Willmott via email: ash.willmott@aru.ac.uk.

7. **Has the study got ethical approval?**

This study has been approved by the Faculty of Science and Engineering Research Ethics Committee, Anglia Ruskin University.

8. **Has the organisation where the research is being carried out given permission?**
Yes, the project will be predominantly undertaken at Anglia Ruskin University, with the analysis of amino acids undertaken at the Danone Global Research & Innovation Center site (project funder).

9. **Legislation relating to this study**

In this study, whole blood samples will be collected via cannulation by a trained researcher or phlebotomist (i.e. blood collector). The serum part of the whole blood samples will then be transferred into 2 separate tubes (*Sample 1* and *Sample 2*), before being frozen and stored in accordance with the Human Tissue Act (2004) at Anglia Ruskin University, Compass House 010b and/or the Human Biomarker Laboratory. Upon completion of the data collection period, all *Sample 1* tubes will be shipped to the Analytical Laboratory Danone Global Research & Innovation center, Utrecht, the Netherlands, for storage and the analysis of the amino acid bioavailability. All *Sample 2* tubes will continue to be stored at Anglia Ruskin University, Compass House 010b and/or the Human Biomarker Laboratory. Upon the completion and confirmation of amino acid bioavailability analysis at the Analytical Laboratory Danone Global Research & Innovation center, Utrecht, the Netherlands, all material/samples, whether used or unused, will be disposed of in accordance with local legislation for both *Sample 1* and *Sample 2*.

10. **What will happen to the results of the study?**

If you agree to take part, your data will be password-protected and pseudo-anonymised via a coding system known only by the research team. Your results will be stored on a password-protected computer and portable disk drive, and your name and other details will be removed. All paper data will be kept securely by the research team at Anglia Ruskin University. The average data for all participants will be used for research purposes only, e.g., research publications or conference presentations, with no reference to individual personal information (names, contact details etc.).

11. **Contact for further information**

For further information, please do not hesitate to contact the lead researcher: ash.willmott@aru.ac.uk.

Section B: Your Participation in the Research Project

1. **What will I be asked to do?**

This study has two parts: 1) an initial pre-screening assessment and 2) complete 3 separate trials where you will be asked to ingest a nutritional test or control product drink. All lab-based sessions will take place at Compass House on East Road, Anglia Ruskin University, Cambridge.

The study design is a three-way, single-blind, randomised, cross-over study design for bioavailability assessment of the amino acid profile of 3 nutritional drinks as outlined below, whereby you will receive either 1 serving of the:

- **Test product**: high protein yoghurt drink (1 serving = 25g protein, 300ml),
- **Control product 1**: micellar casein drink (1 serving = 25g protein, 300 ml),
- **Control product 2**: flavoured water-based placebo drink (1 serving = 0g protein, 300 ml), at each visit, in a randomised order.

<u>Part 1 – Pre-screening assessment:</u>

- This will involve a full study briefing presentation, in which we will go over the outline of the study, including expectations, lab visits and product information.
- Study staff will collect food and exercise diaries from volunteers (a 3-day food and exercise diaries, comprising of 1 weekend day, 1 rest day, and 1 exercise day within a week). If the inclusion criteria are met, participants will continue into the trial.
- Once you have had a chance to ask any questions and should you wish to volunteer, we will ask you to complete 2 consent forms (one for the main study and one for collection of samples as part of our internal processes).
- Next, we will check you meet our study criteria via a standard health screen form as outlined above, along with assessment of your body composition, body mass and height (for body mass index). We will also collect data including, biological sex at birth (male/female), age (years) and lifestyle parameters (alcohol consumption is classified as [on average during the last 6 months] none, ≤ 7 units per week, 8-14 units per week, 15-21 units per week, > 21 units per week, training history including amount of exercise undertaken per week/month [time and frequency] and general information from the health screen questionnaire, and then relevant medical history, prior and concomitant medication, and nutritional supplements. If exclusion criteria are met, participants will be withdrawn from the study.
- Assuming you fully meet our criteria and are willing to take part, we will then provide you with key information and instructions for food diary assessment.
- Following this first assessment, we will then provide you with details to book in for each of the 3 trials.

Part 2 - Main study trials:
The main part of this study will involve 3 visits of >4 hours each, with each visit scheduled no more than 21 days apart.

Outline of each visit

General –
You will be required to refrain from physical activity and alcohol consumption 24 hours before each study visit. The evening before the lab visit, you will be asked to eat a standardised meal to be consumed after 17:00 and arrive the labs after an overnight fast (at least 10 hours). Before arriving at the lab (~7-9am), you can drink up to 500 mL of only water in the morning, but no sooner than 1 hour before each appointment. You will also be required to complete a habitual food diary which will be explained at the briefing session. At the end of each visit, we will undertake product/protocol compliance audits to assess study product intake and adherence to assessment windows during the study visits.

Visit 1 – Upon arrival we will assess your morning body mass. A member of the research team will then fit an intravenous cannula via a short scratch, using a butterfly needle (which is a short, flexible tube that is placed into a vein on your arm or back of your hand) and withdraw 10 mL of blood as a baseline sample. You will then be asked to consume of 1 of 3 drinks (as outlined above), where you will have up to 10 mins to drink the assigned drink. Blood samples will then be drawn at time intervals including 15, 30, 45, 60, 90, 120, 150, 180, 210, and 240 min after the study product intake. This will equate to 11 samples of 10 mL blood collection (within 2 x 5 mL tubes per timepoint), which equals 110 mL blood collection in total per visit (or 330 mL in total over the study). Per trial (110 mL of blood collection) and also over the course of the study (330 mL of blood collection), the amount of blood drawn is less than the maximum permitted extra corporeal volume for male (552-971 mL) and female (486-908 mL) donors of varying body masses and heights (50-100kg, 150-183 cm; JPAC, 2013).

This constitutes the 'bioavailability' test for this study. We will ask you to rest comfortably (please bring something to read or a laptop). Throughout the study visits, you will not be able to eat, but will be permitted to drink water ad libitum after the first 2 hours (with a maximum of 250 mL) – the volume consumed at visit trial 1 will be replicated on subsequent visits. In addition, you will be asked to abstain from any physical exercise other than incidental walking during the study visits.

Visits 2 and 3 – will be at least 5 days apart but no more than 21 days between a visit**;** you will undergo the same protocol method as outlined above, with a different study product.

About the nutrition products we will assessing:
This study is a project being undertaken between Anglia Ruskin University and Danone Global Research & Innovation Center, Netherlands. All products will be supplied independently by Danone Global Research & Innovation Center as a nutrition company and have been verified for human consumption and safety. All ingredients are commonly found in food, with the main test product available in supermarkets. For the purposes of this study, we will be using 3 different products in a random order:

- **Test product**: high protein yoghurt drink (1 serving = 25g protein, 300ml) that is found in supermarkets throughout the UK,
- **Control product 1**: micellar casein drink (1 serving = 25g protein, 300 ml), which is a protein supplement that is the predominant protein in cow's milk.
- **Control product 2**: flavoured water-based placebo drink (1 serving = 0g protein, 300 ml),

What are my samples being assessed for?

We will collect blood samples and analyse them only for the markers listed below. We will be assessing your amino acids (the building blocks of proteins) in your blood in response to the test drink. Whilst you don't need to worry about all the names, we have listed them here for completeness:

- Essential Amino Acids (histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, and valine),
- Total Amino Acids (alanine, arginine, asparagine, aspartic acid, citrulline, cysteine, glutamic acid, glutamine, glycine, histidine, isoleucine, leucine, lysine, methionine, ornithine, phenylalanine, serine, taurine, threonine, tryptophan, tyrosine, valine, and proline)

These markers will be assessed at Danone Global Research & Innovation Center, Netherlands. All samples count as 'human tissue' and will therefore be collected, stored and disposed of in accordance with the Human Tissue Act (HTA: 2004) and internal processes at Anglia Ruskin University and Danone Global Research & Innovation Center, Netherlands, respectively. All samples will be pseudo-anonymous and stored under the participant ID code. Only the research team can access the information linking the participant ID and individual. This information will be kept on a secure, password-protected ARU laptop and will not be shared with anyone else. All signed consent forms will be kept in a locked cabinet located in a restricted-access office.

Finally, participants will be contacted within 7 days after completion of the study to follow up on any Serious Adverse Events that may have occurred – e.g. incidence, frequency, seriousness, severity, and relatedness of any product/method undertaken as part of the study.

2. **In relation to this specific research project, we need to make you aware of the following:**

☐	We do not need your personal data at any stage of this research project		
We are responsible for the personal data you give to us as a:			
X	**Data Controller** (We are in sole control over the research)	Who are we?:	Dr Ash Willmott Dr Sanjoy Deb Mr Dirk Dugdale Anglia Ruskin University
X	**Joint Controller** (Where ARU and another organisation are working together on research)	with:	Danone Global Research & Innovation Center.
☐	**Data Processor** (Where the data will belong to another organisation and ARU is being engaged under contract/ agreement to conduct the research and provide an outcome but has no rights over the personal data)	on behalf of:	

3. **I will be asking you for the following information:**

Personal Data				Sensitive Personal data	
✓	Name / Contact details (email address)	☐	Image (Photo or video)	✓	Racial/ Ethnicity data
✓	Age	☐	Experiences	☐	Political/ Religious beliefs
☐	Location data	☐	Opinions	☐	Trade Union membership
☐	Employment & Earnings	✓	Serum amino acids	☐	Genetic/ Biometric data
☐	ID Numbers (e.g. NHS)	☐	[Other]	✓	Health data as outlined below
☐	Online identifier	☐	[Other]	☐	Sex life/ orientation data

The health data we intend to collect will include:

- Demographics
  - Biological sex at birth (male/female),
  - Age (years).
- Anthropometry
  - Height (m) via SECA scale,
  - Body mass (kg) via SECA scale,
  - Lean tissue mass (kg) and fat mass (kg and % body mass) using Bod Pod, 4-site skinfold thickness and/or Bioelectrical Impedance scales,
  - BMI (kg/m^2) via equation: dividing body mass (kg) by height (m^2).
- Lifestyle parameters
  - Alcohol consumption is classified as (on average during the last 6 months) none, ≤ 7 units per week, 8-14 units per week, 15-21 units per week, > 21 units per week,
  - Training history including amount of exercise undertaken per week/month (time and frequency).
  - General information from the health screen questionnaire, and then relevant medical history, prior and concomitant medication, and nutritional supplements.
  - Participants will be asked to complete a 3-day food and exercise diaries, comprising of 1 weekend day, 1 rest day, and 1 exercise day within a week.
- Serum amino acids
  - Essential Amino Acids (histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, and valine),
  - Total Amino Acids (alanine, arginine, asparagine, aspartic acid, citrulline, cysteine, glutamic acid, glutamine, glycine, histidine, isoleucine, leucine, lysine, methionine, ornithine, phenylalanine, serine, taurine, threonine, tryptophan, tyrosine, valine, and proline)

4. **What will happen to your data?**

All data, samples and information collected from you as part of this study will be pseudo-anonymous and stored under the participant ID code, current legislation and Anglia Ruskin University policy. Only the research team can access the information linking the participant ID and individual. This information will be kept on a secure, password-protected ARU laptop and will not be shared with anyone else. All signed consent forms will be kept in a locked cabinet located in a restricted-access office.

Serum blood samples (*Sample 1* and *Sample 2*), will be frozen and stored in accordance with the Human Tissue Act (2004) at Anglia Ruskin University, Compass House 010b and/or the Human Biomarker Laboratory. Upon completion of the data collection period, all *Sample 1* tubes will be shipped to the Analytical Laboratory Danone Global Research & Innovation center, Utrecht, the Netherlands, for storage and the analysis of the amino acid bioavailability. All *Sample 2* tubes will continue to be stored at Anglia Ruskin University, Compass House 010b and/or the Human Biomarker Laboratory. Upon the completion and confirmation of amino acid bioavailability analysis at the Analytical Laboratory Danone Global Research & Innovation center, Utrecht, the Netherlands, all material/samples, whether used or unused, will be disposed of in accordance with local legislation for both *Sample 1* and *Sample 2*. The study will be written up using the information and data collected as part of a research publication in a scientific journal.

5. **Will I be reimbursed travel expenses?**

No – we unfortunately will not fund travel expenses for this study.

6. **Will I receive any payment to take part in the research?**

Yes – participants will receive food vouchers (£45 in total) to undertake recommended diets over testing period. This includes 3 standardised dinners which are to be consumed after 17:00 the evening prior to each study visit. These vouchers will be used within regular supermarkets (e.g. Tesco) for the purchasing of the recommended diets. Support, information and guidance will be provided to the participants for the recommended diets.

In addition, upon completion of all 3 trials there is an individual subsidy of £75 Amazon vouchers per person based on the recognised commitment for this study.

7. **Are there any possible disadvantages or risks to taking part?**

Research of this nature has a number of potential risks. However, every effort has been made to minimise the nature of these risks and ensure your wellbeing. Risk assessments have been carried out for all procedures in this study. Whilst we highlight the exclusion criteria above and key risks associated with this study below, we would also like to remind/bring these points to the reader's attention here when considering their participation for this study –

1) Any participants with known dietary allergies will be excluded.
2) Any participants with known intolerances to ingredients of the study product, i.e. dairy, cow's milk allergies, lactose intolerance, will be excluded.
3) Participants with distress/fears/negative experience or unsure/uncertain on the associated requirements for blood samples and use of needles and/or cannulas, will be excluded.

Possible risks associated with this study include:

- ***Blood collection*** - possible risks include: dizziness/fainting/ nausea, localised bruising/swelling and contamination/infection. Samples will only be collected by qualified

researchers who are highly experienced in taking blood samples. Only in-date, sterilised, equipment will be used.

- ***Nutrition products*** - with any nutrition product, the following risks are possible albeit unlikely: contamination of products, acute side effects (nausea, dizziness, bloating and/or gastrointestinal distress from consumption) or allergic or adverse reaction to the product. Products will only be sourced from a nutrition company for safe public consumption. Should you experience any adverse reactions to either food product, please advise the researcher or principal investigator immediately (Dr Ash Willmott).

- ***General data*** – there is the risk of 'disclosure of personal information'; however, this is very unlikely as confidentiality will be maintained for all participants throughout the study using number coding instead of personal details. All data associated with this study will be password protected and fully anonymised for confidentiality.

8. **What are the likely benefits of taking part?**

Whilst this type of research will be used to support/design future studies on recovery strategies and the product's efficacy, we will be providing you with information pertinent to your dietary analysis, which you might find useful to your day-to-day lifestyle. Once all the data has been compiled, we will share your individual data with you which will let you know more about how you responded to the nutritional drinks.

9. **Can I withdraw at any time, and how do I do this?**

You can withdraw from the study at any time and without giving a reason. Should you decide to withdraw from the study during or following your participation for any reason, please contact the researcher or principle investigators via email - Dr Ash Willmott: ash.willmott@aru.ac.uk.

10. **What will happen to my data?**

Our general privacy notice explaining our use of your personal data for research purposes is available here:

https://www.anglia.ac.uk/privacy-and-cookies/research-participants

Please visit this link for information about how long we keep your data, how we keep it secure, how you can exercise your rights over your data, and how you can make a complaint about our use of your data.

11. **Can I withdraw my data from the study?**

If you wish to withdraw from the research, please speak to the researcher or email them at ash.willmott@aru.ac.uk stating the title of the research or send them this withdrawal slip. You do not have to give a reason for why you would like to withdraw. Please let the researcher know whether or not you are happy for the data collected so far to be used in the research. You are completely free to ask for any data to also be removed should you wish it to be, if the data is not anonymised. When data is anonymised upon full data collection (estimated November 2025), it means personal data relating to it has been permanently removed, so the researcher will not know which belongs to you. You do not have to answer any questionnaire or interview questions you do not wish to.

12. **Whether there are any special precautions you must take before, during or after taking part in the study**

As outlined above, before each laboratory visit, you will be required to consume a standardised meal, which will be provided and outlined at the pre-screening assessment, which needs to be consistent prior to all lab visits. You will be asked to refrain from physical activity and alcohol consumption 24 hours before each study visit. You will also need to overnight fast (10 hours), consuming only water (up to 500 mL) no less than 1 hour before arrival for testing and avoid the consumption of any stimulants or protein formulas which may conflict with the study parameters (e.g. caffeine, energy drinks or whey protein shakes). If your health status changes, or you start taking medication or other supplements during the study, please let us know as soon as possible.

13. **Will I pass onto anyone else what you have told me?**

The only people who will be able to access your data (as outlined above), will be the principal investigator (Dr Ash Willmott) and members of the immediate research team, as well as Danone Global Research & Innovation Center. All data will be pseudo-anonymised and so your name will not be stored or shared. Only the immediate research team will have access to participants names and ID codes. This will not be shared any further.

14. **Summary of research findings**

A summary of the research findings will be available and can be provided to you, if you wish, after the study is completed. This can be arranged after the study is completed. The summary of research findings can be sent to you via email.

15. **Contact details for complaints**

If you have any complaints about the study, please contact ash.willmott@aru.ac.uk in the first instance. There are also, however, details about ARU's complaints procedure should you wish to use it. Email address: complaints@aru.ac.uk. Postal address: Office of the Secretary and Clerk, Anglia Ruskin University, Bishop Hall Lane, Chelmsford, Essex, CM1 1SQ.

Version control = Date 01.2.25 V1.2
Your participant information sheet, consent form and other documents should have a version number and date. This is in order that should any changes be required by the ethics committee, it is clear which documentation has ethical approval.

PARTICIPANT CONSENT FORM

NAME OF PARTICIPANT:

Title of the project: BOLT STUDY Part A: The effects of commercially available high protein drink on amino acid bioavailability in 18-45-year-old male and female participants

Main investigator and contact details: Dr Ash Willmott (ash.willmott@aru.ac.uk)

Members of the research team: Dr Sanjoy Deb, Mr Dirk Dugdale.

1. I agree to take part in the above research. I have read the Participant Information Sheet (**Date 01.02.25 V2**) for the study. I understand what my role will be in this research, and all my questions have been answered to my satisfaction.

2. I understand that I am free to withdraw from the research at any time, without giving a reason. To do this I understand I can use the withdrawal slip below or email the main investigator.

3. I understand I am free to ask any questions at any time before and during the study.

4. I understand what information will be collected from me for the study.

5. I understand what will happen to the data collected from me for the research. All blood samples will be collected, analysed and disposed of in accordance with the Human Tissue Act.

6. For the purposes of the General Data Protection Regulation (2018), if this project requires me to produce personal data, I have read and understood how Anglia Ruskin University will process it.

7. I have been told about any disadvantages or risks regarding me taking part.

8. I have been informed how my data will be processed, how long it will be kept and when it will destroyed.

9. I have been provided with a copy of this form and the Participant Information Sheet (**Date 01.02.25 V2**).

Name of participant (print)……

Signed……..…..

Date……

I WISH TO WITHDRAW FROM THIS STUDY.

Title of the project: BOLT STUDY: The effects of commercially available high protein drink on amino acid bioavailability in 18-45-year-old male and female participants

If you wish to withdraw from the research, please speak to the researcher or email them Dr Ash Willmott - ash.willmott@aru.ac.uk, stating the title of the research or send them this withdrawal slip.

You do not have to give a reason for why you would like to withdraw.

Date 01.02.25
V2

PARTICIPANT INFORMATION SHEET

Please take the time to review this document and ask any questions you may have about the study before volunteering to take part.

Section A: The Research Project

12. **Title of project: BOLT Part B:** The effects of commercially available high protein drink on recovery from muscle fatiguing exercise in 18-45-year-old male and female participants.

13. **Purpose of study**

Part B of the BOLT study will examine the effect of a twice-daily ingestion of 1) high protein yoghurt drink (test product), or 2) flavoured water based drink (control drink) on biomarkers of 1) muscle damage/stress, 2) physical function, 3) self reported pain and muscle soreness, and 4) range of motion, sleep, and recovery assessments, at 24, 48, and 72 hours following acute muscle fatiguing exercise in 18-45-year-old male and female participants. Participants will be randomly allocated to the test product or control drink groups prior to beginning the first visit.

The results will provide novel insights into the efficacy of protein drinks on markers of exercise and may enable future application in products available to the consumer. Therefore, the main aim of this study is to compare the effectiveness of the consumption of a high protein yoghurt drink to a flavoured water-based placebo drink on changes in blood biomarkers and markers of recovery 24, 48, and 72 hours after a fatiguing exercise protocol.

This research study is being undertaken by Anglia Ruskin University, in Cambridge in collaboration with a world-leading nutrition company, Danone Global Research & Innovation Center, in the Netherlands.

14. **Who is the researcher?**

This project is being undertaken by Dr Ash Willmott, Mr Dirk Dugdale and Dr Sanjoy Deb at the Cambridge Centre for Sport and Exercise Sciences at Anglia Ruskin University.

15. **Why have I been asked to participate?**

You are being invited to take part in this research study based on your interest in the area and as a generally healthy adult. Before you decide whether to do so, it is important that you understand the research that is being undertaken and what your involvement will include. Please take the time to read the following information carefully and discuss it with others if you wish. Do not hesitate to ask us anything that is not clear or for any further information you would like to help you would like to help make your decision. Please do take your time to decide whether or not you wish to take part. Thank you for reading this.

There are a number of key inclusion criteria listed below, please check that all apply to you:

<u>Inclusion criteria</u>

- Age ≥ 18 and ≤ 45 years.
- Body Mass Index (BMI) ≥ 18.5 and ≤ 29.9 kg/m^2 (measured at the first assessment),
- Written informed consent (undertaken at the first assessment).
- Willingness and ability to comply with the protocol in the opinion of the investigator.
- Judged by the investigator to be in good health as assessed by a health screening questionnaire.
- Currently identifies as the same biological sex as at birth.

As with any study, there are also important exclusion criteria which will prevent you from being able to take part in this study – please check that none of these apply to you. **Unfortunately, if any criteria apply to you, you will be unable to participate in this research study.**

Exclusion criteria:

- Any known ongoing medical condition that might interfere with absorption and digestion and/or gastrointestinal (GI) function (e.g. inflammatory bowel disease, gastroesophageal reflux disease, celiac disease, diaphragmatic hernia or diaphragmatic surgery, gastric ulcer, gastritis, gall bladder problems, pancreatitis, GI cancer, oesophageal and/or gastric surgery).), in opinion of the investigator,
- Known musculoskeletal or soft tissue injury.
- Known cardiovascular disease, disease related to the immune system and/or the respiratory system.
- Known renal or hepatic failure or known thyroid dysfunction.
- Known Diabetes Mellitus type I or type II, insulin resistance or metabolic syndrome.
- Any ongoing cancer (except for basal cell carcinoma) and/ or cancer treatment,
- Known anaemia or low haemoglobin or low iron status.
- Any known bleeding disorder or reaction to withdrawal of blood samples.
- Use of oral and systemic use of prokinetics, laxatives, antidiarrheals, anticoagulants within 2 weeks prior to screening.
- Use of systemic antibiotics within 4 weeks prior to screening.
- Any known dietary allergies.
- Any known intolerances to ingredients of the study product, i.e. dairy, cow's milk allergies, lactose intolerance.
- Self-reported adherence to a strict dietary regime (e.g. vegetarian/ vegan/ paleo/ketogenic/intermittent fasting/ high protein diet (>1.6 g/kg body weight/day), or protein supplementation or a weight loss program, as confirmed via the screening process.
- Use of any nutritional supplements or additional protein supplements or nutritional support within 4 weeks prior to screening.
- Engage (on average) in more than 2 resistance exercise sessions and/or more than 4 exercise sessions in total weekly within 2 months before screening,
- Considered as endurance trained, competitive athletes or trained weightlifters, powerlifters or bodybuilders, in the opinion of the investigator.
- Known pregnancy and/or lactating.
- Current smoking or stopped smoking for <1 month prior to screening (except for incidental smoking of ≤3 cigarettes/cigars/pipes per week on average in the last month).
- Average alcohol use of >21 glasses* per week for men or >14 glasses per week for women (on average during the last 6 months) or drug/ medicine abuse in opinion of the investigator.
- Participation in any other clinical study with investigational or marketed products concomitantly or within 4 weeks before screening.
- Major medical or surgical event requiring hospitalization within the preceding 3 months and/or scheduled in the period of study participation relevant in the opinion of the investigator.

Note: *1 glass of alcohol is a standard serving per type of alcohol. According to the Centres for Disease Control and Prevention 1 drink is defined as 340 ml of 5% ABV beer, 142 ml of 12% ABV wine, 43 ml of 40% ABV distilled spirits or liquor.

16. **How many people will be asked to participate?**

For this part of the study, approximately 50 people will be invited to participate. Whilst this is an acute short-term study, it involves 4 visits of ~2 hours each, across 4 consecutive days, we are looking for reliable individuals who will be willing to complete all aspects of the study based on the nature of the project.

17. **Do I have to take part?**

Participation is completely voluntary, and you have the right to withdraw at any time without providing reason or judgment. To withdraw, please use the form at the bottom of the consent form provided or contact the Principal Investigator - Dr Ash Willmott via email: ash.willmott@aru.ac.uk.

18. **Has the study got ethical approval?**

This study has been approved by the Faculty of Science and Engineering Research Ethics Committee, Anglia Ruskin University.

19. **Has the organisation where the research is being carried out given permission?**

All research will be undertaken with approval from the Laboratory Director/Manager, within Anglia Ruskin University, Sport and Exercise Science Human Physiology Laboratory, Compass House, in Cambridge. In addition, this project will be carried out under human tissue authority regulations in compliance with university guidelines to ensure your blood samples collected within this study are kept confidential and secure.

20. **Legislation relating to this study**

In this study, 5 x 10 mL whole blood samples will be collected via venepuncture by a trained researcher or phlebotomist (i.e. blood collector) - twice on visit 2 and once on visits 3-5 (= 50 mL of whole blood in total per participant). The amount of blood drawn is less than the maximum permitted extra corporeal volume for male (552-971 mL) and female (486-908 mL) donors of varying body masses and heights (50-100kg, 150-183 cm; JPAC, 2013). The serum/plasma part of the whole blood samples will then be transferred into separate tubes for each biomarker. We will be assessing 5 biomarkers in total - creatine kinase, cortisol, myoglobin, C-reactive protein and interleukin-6. For each serum/plasma tube there will be 2 separate samples = *Sample 1* and *Sample 2*, which will be frozen and stored in accordance with the Human Tissue Act (2004) at Anglia Ruskin University, Compass House 010b and/or the Human Biomarker Laboratory. Upon completion of the data collection period, all *Sample 1* tubes will be analysed for muscle damage/inflammatory and stress biomarkers at Anglia Ruskin University or shipped to the Core Biochemical Assay Laboratory at Addenbrookes Hospital, Cambridge, UK, for storage and the analysis of the muscle damage/inflammatory and stress biomarkers. All *Sample 2* tubes will continue to be stored at Anglia Ruskin University, Compass House 010b and/or the Human Biomarker Laboratory. Upon the completion of muscle damage/inflammatory and stress biomarker analysis at Anglia Ruskin University or the completion and confirmation of the muscle damage/inflammatory and stress biomarkers analysis at the Core Biochemical Assay Laboratory at Addenbrookes Hospital, Cambridge, UK, all material/samples, whether used or unused, will be disposed of in accordance with local legislation for both *Sample 1* and *Sample 2*.

21. **What will happen to the results of the study?**

If you agree to take part, your data will be password protected and pseudo-anonymised via a coding system known only by the lead researcher. Your results will be stored on a password protected computer and portable disk drive, with your name and other details removed. All paper data will be kept securely by the research team at Anglia Ruskin University. The average data for all participants will be used for research purposes only e.g. research publication or conference presentation, with no reference to individual personal information (names etc.).

22. **Contact for further information**

For further information, please do not hesitate to contact the lead researcher: ash.willmott@aru.ac.uk.

Section B: Your Participation in the Research Project

3. **What will I be asked to do?**

This study has two parts: 1) an initial pre-screening assessment and 2) complete 4 separate trials where you will be asked to ingest a nutritional test or control product drink. All lab-based sessions will take place at Compass House on East Road, Anglia Ruskin University, Cambridge.

The study is an exploratory interventional study, utilising double blind, randomised, parallel group design for the assessment of a nutritional drink as outlined below on the recovery from acute muscle fatiguing exercise protocol. Participants will receive 2 servings of a **Test product:** high protein yoghurt drink (1 serving = 25g protein, 300 ml) or a **Control product:** flavoured water-based placebo drink (1 serving = 0g protein, 300 ml), per day for 3 days over the course of the study.

Participants will receive a copy of this information on the study, to read over and decide upon their voluntary participation. If interest, participants will be requested to complete 3-day food and exercise diaries (as outlined/provided below), comprising of 1 weekend day, 1 rest day, and 1 exercise day within a week before attending the pre-screening assessments where they will be asked to provide their consent for participation.

Having read this form and followed the procedure above, we will ask you to attend a full study briefing and pre-screening assessment as follows:

Visit 1:
Part 1 – Pre-screening assessment:

- This will involve a full study briefing presentation, in which we will go over the outline of the study, including expectations, lab visits and product information. Participants will refrain from physical activity and alcohol consumption 24 hours before the familiarisation visit.
- Study staff will collect food and exercise diaries from volunteers. If the inclusion criteria are met, participants will continue into the trial.
- Once you have had a chance to ask any questions and should you wish to volunteer, we will ask you to complete 2 consent forms (one for the main study and one for collection of samples as part of our internal processes).
- Next, we will check you meet our study criteria via a standard health screen form as outlined above, along with assessment of your body composition, body mass and height (for body mass index). We will also collect data including, biological sex at birth (male/female), age (years) and lifestyle parameters (alcohol consumption is classified as [on average during the last 6 months] none, ≤ 7 units per week, 8-14 units per week, 15-

21 units per week, > 21 units per week, training history including amount of exercise undertaken per week/month [time and frequency] and general information from the health screen questionnaire, and then relevant medical history, prior and concomitant medication, and nutritional supplements. If exclusion criteria are met, participants will be withdrawn from the study.

- Assuming you fully meet our criteria and are willing to take part, we will then provide you with key information and instructions for food diary assessment.
- Participants will then undergo familiarisation of the primary dependent measures and exercises (as outlined below) that will be completed during the study. Study staff will measure participants' body mass and hydration status, and maximal voluntary contraction (MVC) of knee extension/flexion. Study staff will familiarise participants with the perceived pain threshold test, range of motion (ROM) test, 75% of MVC, drop jumps, 30 second counter movement jump (CMJ30), and 6 second peak power test (PPT6).
- Participants will be informed of the set standardised meals for breakfast, lunch and dinner across visit 2-5 and will be asked to keep their habitual physical activity pattern of no more than 4 exercise sessions per week, of which no more than 2 sessions are light resistance exercise sessions. Between visit 2-5 participants will be asked not engage in exercise, except for the exercise that is part of this study. Participants will record any deviations from the standardised meal plan in a food compliance diary throughout.
- Participants will be randomly allocated to receive either the test product or the control product.
- Following this first assessment, we will then provide you with details to book in for each of the 4 trials.

Part 2 - Main study trials:

The main part of this study will involve 4 visits of ~2 hours each, across 4 consecutive days, occurring at the same time of day.

Outline of each visit

General – Participants will be required to refrain from physical activity and alcohol consumption 24 hours before each study visit. Participants will be asked to adhere to the recommended standardised meals for breakfast, lunch and dinner across visit 2-5. Between visit 2-5, participants will be asked not engage in exercise, except for the exercise that is part of this study. Participants will record any deviations from the standardised meal plan in a food compliance diary throughout.

After an overnight fast (at least 10 hours) for each visit, participants will come to the study site to participate in the study visit. Before arriving to our lab, you can drink up to 500 mL of only water in the morning. You will also be required to complete a habitual food diary which will be explained at the briefing session. At the end of each visit, we will undertake product/protocol compliance audits to assess study product intake at the study visits and adherence to assessment windows.

Visit 2 – Upon arrival to the laboratories, participants will be asked to provide their completed food compliance diary. Study staff will then measure participants body mass, hydration status and collect one 10 mL whole blood sample via venepuncture by a trained researcher or phlebotomist (i.e. blood collector). Participants will complete the sleep quality questionnaire, recovery questionnaires, perceived pain threshold test, record heart rate variability (HRV) and range of motion (ROM) test. Next, participants will complete maximal voluntary contraction (MVC), 75% of MVC, 30 second countermovement jump (CMJ30) test and a 6 second peak power output test (PPT6). Participants will then complete the muscle fatiguing exercise protocol (6 sets, whilst wearing a weighted vest) of 25 drop jumps, with passive rest between sets. Study staff will measure the participants' rating of perceived exertion (RPE) and heart rate before,

during and after the protocol, as well as a capillary blood lactate concentration from the participants' fingertip immediately before and after the protocol. Participants will then repeat the baseline protocol (e.g. blood sample, perceived pain threshold, ROM, MVC, CMJ30 and PPT6 tests). Within 30-min after the acute muscle fatiguing exercise protocol, participants will consume the first serving of the study product at the site.

Before leaving the study site, participants will receive recommendations for standardised meals for the next 3 days, the second serving of the study product, and study product compliance diaries. In the afternoon, participants will consume standardised lunch, test or control product and dinner (described below).

Visit 3, 4 and 5 – On visit 3-5, participants will attend the laboratory once again and return completed food compliance diaries and study product intake compliance diaries from the previous day and receive the same empty diaries for the next day. On visit 3-5 study staff will again measure the participants' body mass, hydration status and draw a 10 mL venous blood sample. Participants will then complete the sleep quality questionnaire, recovery questionnaire, perceived pain threshold test, record HRV and range of motion test. Next, participants will complete MVC, 75% of MVC, CMJ30, and PPT6 tests. Within 30-min testing, participants will consume the study product at the site. Participants will consume a standardised lunch, the second serving of the study product, and dinner at home. On visit 5, participants will end the study after the performance and fatigue measures followed by lunch.

About the nutrition products we will assessing:

This study is a major project being undertaken between Anglia Ruskin University and Danone Global Research & Innovation Center, in the Netherlands. All products will be supplied independently by Danone Global Research & Innovation Center as a world-leading nutrition company and have been verified for human consumption and safety. For the purposes of this study, there will be 2 parallel groups undertaking 1 of 2 different products:

- **Test product**: high protein yoghurt drink (1 serving = 25g protein, 300 ml),
- **Control product**: flavoured water-based placebo drink (1 serving = 0g protein, 300 ml)

What are my samples being assessed for?

For this study we will be collecting 5 x 10 mL blood samples – 2 x 10 mL per visit 2 and 1 x 10 mL per visits 3-5. We will only be analysing for the markers listed below.

- Venous blood for muscle damage/stress biomarkers – creatine kinase, cortisol, myoglobin, C-reactive protein and interleukin-6.

We will also be collecting 2 x fingertip capillary blood for metabolic changes pre-to-post exercise. This sample will be analysed for blood glucose and lactate at the point of collection and immediately disposed of.

These markers will be assessed at Anglia Ruskin University or Addenbrookes hospital Core Biochemical Assay Laboratory, Cambridge (for venous blood) and ARU laboratories (for capillary blood). The samples you provide count as 'human tissue' and will therefore be collected, stored and disposed of in accordance with the human tissue act and our internal processes here at Anglia Ruskin University. All samples are coded (only known to the research team) so it will not be possible to identify you specifically.

Finally, participants will be contacted within 7 days after completion of the study to follow up on any Serious Adverse Events that may have occurred– e.g. Incidence, frequency, seriousness, severity, and relatedness of any product/method undertaken as part of the study.

4. **In relation to this specific research project, we need to make you aware of the following:**

☐	We do not need your personal data at any stage of this research project		
We are responsible for the personal data you give to us as a:			
☐	**Data Controller** (We are in sole control over the research)	Who are we?:	Dr Ash Willmott Dr Sanjoy Deb Mr Dirk Dugdale Anglia Ruskin University Blood sampling only: Anglia Ruskin University or Addenbrookes hospital Core biochemical assay laboratory
X	**Joint Controller** (Where ARU and another organisation are working together on research)	with:	Danone Global Research & Innovation Center, in the Netherlands
☐	**Data Processor** (Where the data will belong to another organisation and ARU is being engaged under contract/ agreement to conduct the research and provide an outcome but has no rights over the personal data)	on behalf of:	

16. **I will be asking you for the following information:**

Personal Data				**Sensitive Personal data**	
✓	Name/ Contact details (email address)	☐	Image (Photo or video)	✓	Racial/ Ethnicity data
✓	Age	☐	Experiences	☐	Political/ Religious beliefs
☐	Location data	☐	Opinions	☐	Trade Union membership
☐	Employment & Earnings	✓	Exercise test data as outlined below	☐	Genetic/ Biometric data
☐	ID Numbers (e.g. NHS)	☐	[Other]	✓	Health data as outlined below
☐	Online identifier	☐	[Other]	☐	Sex life/ orientation data

The **health data** we intend to collect will include:

- Demographics
    - Biological sex at birth (male/female),
    - Age (years).
- Anthropometry
    - Height (m) via SECA scale,
    - Body mass (kg) via SECA scale,
    - Lean tissue mass (kg) and fat mass (kg and % body mass) using Bod Pod, 4-site skinfold thickness and/or Bioelectrical Impedance scales,
    - BMI (kg/m^2) via equation: dividing body mass (kg) by height (m^2).
- Lifestyle parameters
    - Alcohol consumption is classified as (on average during the last 6 months) none, ≤ 7 units per week, 8-14 units per week, 15-21 units per week, > 21 units per week,
    - Training history including amount of exercise undertaken per week/month (time and frequency).
    - General information from the health screen questionnaire, and then relevant medical history, prior and concomitant medication, and nutritional supplements.
- Product/Protocol Compliance
    - Study product intake at the study visits,
    - Adherence to assessment windows.

The **exercise test data** we intend to collect will include:

- The change from baseline in peak torque [Nm] assessed by isometric/isokinetic maximum voluntary contraction (MVC) of knee extension/flexion at 120 degrees/second using an isokinetic dynamometer,
- The change from baseline in the number of repetitions to failure assessed by 75% of isokinetic MVC of knee extension/flexion using an isokinetic dynamometer,
- The change from baseline in relative mean power [W/kg of body mass] and fatigue index [n/%] assessed by countermovement jumps for 30s (CMJ30),
- The change from baseline in a peak power output [W], fatigue index [%] and time to reach peak power [s] assessed by the 6-second peak power test (PPT6) on a cycle ergometer,
- The change from baseline in perceived recovery [score] assessed using the Perceived Recovery Status (PRS) scale and visual analogue scale to evaluate fatigue severity (VAS-F),
- The change in subjective pain (DOMS) as assessed by a visual analogue over time between and within the two groups,
- The change from baseline in blood biomarker concentrations
    - serum/plasma CK concentration [IU/L or another unit],
    - serum/plasma myoglobin concentration [ng/mL or another unit],
    - serum/plasma interleukin-6 (IL-6) concentration [pg/mL or another unit],
    - serum/plasma C-reactive protein (CRP) concentration [mg/L or another unit],
    - serum/plasma cortisol [nmol/L or another unit],
- Change from baseline in main muscle group and total perceived pain threshold [kgf] assessed using an algometer,
- Change from baseline in stiffness and mobility [°flexion] of the knee extensors of the dominant leg assessed by ROM using a goniometer,
- The change from baseline in sleep quality via the Consensus Sleep Diary.

- Heart rate variability (HRV).
- Heart rate, RPE and blood lactate/glucose pre, during and after the fatiguing protocol.

17. **What will happen to your data?**

Any information/data collected from you as part of the study will pseudo-anonymised and stored in accordance with current legislation and Anglia Ruskin University policy. The serum and plasma part of the whole blood samples will be transferred into 2 separate tubes (*Sample 1* and *Sample 2*), before being frozen and stored in accordance with the Human Tissue Act (2004) at Anglia Ruskin University, Compass House 010b and/or the Human Biomarker Laboratory. Upon completion of the data collection period, all *Sample 1* tubes will be analysed for muscle damage/inflammatory and stress biomarkers at Anglia Ruskin University or shipped to the Core Biochemical Assay Laboratory at Addenbrookes Hospital, Cambridge, UK, for storage and the analysis of the muscle damage/inflammatory and stress biomarkers. All *Sample 2* tubes will continue to be stored at Anglia Ruskin University, Compass House 010b and/or the Human Biomarker Laboratory. Upon the completion of muscle damage/inflammatory and stress biomarker analysis at Anglia Ruskin University or the completion and confirmation of the muscle damage/inflammatory and stress biomarkers analysis at the Core Biochemical Assay Laboratory at Addenbrookes Hospital, Cambridge, UK, all material/samples, whether used or unused, will be disposed of in accordance with local legislation for both *Sample 1* and *Sample 2*. The study will be written up using the information and data collected as part of a research publication in a scientific journal. It will not be possible to identify individual participants from any outputs. As part of the study collaboration with Danone Global Research & Innovation Center, in the Netherlands, essential data will be shared with the Clinical Nutrition Team, generically, i.e. it will not be possible to identify you personally in any of the datasets.

18. **Will I be reimbursed travel expenses?**

No.

19. **Will I receive any payment to take part in the research?**

Yes – Participants will receive food vouchers (£120 in total) to undertake recommended diets over the 4 day testing period: Breakfast x 1, Lunch x 4, Dinner x 4. These vouchers will be used within regular supermarkets for the purchasing of the recommended diets. Support, information and guidance will be provided to the participants for the recommended diets. On completion of the study, participants will also receive a gift voucher (£100) as an incentive for participation. Time will be allocated to understand participation, to answer questions and discuss these incentives.

20. **Are there any possible disadvantages or risks to taking part?**

Research of this nature has a number of potential risks, however every effort has been made to minimise the nature of these risks and ensure your wellbeing. Risk assessments have been carried out for all procedures in this study.
Whilst we highlight exclusion criteria above and key risks associated with this study below, we would also like to remind/bring these points to the readers attention here when considering their participation for this study:

1) Participants with known dietary allergies will be excluded,

2) Participants with known intolerances to ingredients of the study product, i.e. dairy, cow's milk allergies, lactose intolerance, will be excluded,

3) Participants with distress/fears/negative experience or unsure/uncertain on the associated requirements for blood samples and use of needles and/or cannulas, will be excluded, and

4) Participants injured/unbale to complete exercise testing will be excluded.

Possible risks associated with this study include:

- **Exercise testing** – possible risks include localised muscle soreness/damage/swelling, moderate fatigue, tiredness, dehydration, dizziness,

- ***Blood collection*** - possible risks include: dizziness/fainting/ nausea, localised bruising/swelling and contamination/infection. Samples will only be collected by qualified researchers who are highly experienced in taking blood samples. Only in-date, sterilised, equipment will be used.

- ***Nutrition products*** - with any nutrition product the following risks are possible albeit unlikely: contamination of products, acute side effects (nausea, dizziness, bloating and/or gastrointestinal distress from consumption) or allergic or adverse reaction to product. Products will only be sourced from a world leading nutrition company for safe public consumption. Should you experience any adverse reactions to either food product please advise the principal investigator immediately (Dr Ash Willmott).

- ***Food diary collation/ and general data*** – there is the risk of 'disclosure of personal information'; however, this is very unlikely as confidentiality will be maintained for all participants throughout the study using number coding instead of personal details. All data associated with this study will be password protected and fully anonymised for confidentiality.

21. **What are the likely benefits of taking part?**

Whilst this type of research will be used to support/design future studies on recovery strategies and the product's efficacy, we will be providing you with information pertinent to your dietary analysis, which you might find useful to your day-to-day lifestyle, and your exercise testing data, which you might find useful for your own training interest. Once all the data has been compiled, we will share your individual data with you which will let you know more about how you responded to the nutritional drinks.

22. **Can I withdraw at any time, and how do I do this?**

You can withdraw from the study at any time and without giving a reason. Should you decide to withdraw from the study during or following your participation for any reason, please contact the principle investigators via email - Dr Ash Willmott: ash.willmott@aru.ac.uk.

23. **What will happen to my data?**

Our general privacy notice explaining our use of your personal data for research purposes is available here:

https://www.anglia.ac.uk/privacy-and-cookies/research-participants

Please visit this link for information about how long we keep your data, how we keep your data secure, how you can exercise your rights over your data, and make a complaint over our use of your data.

24. **Can I withdraw my data from the study?**

If you wish to withdraw from the research, please speak to the researcher or email them at ash.willmott@aru.ac.uk stating the title of the research or send them this withdrawal slip. You do not have to give a reason for why you would like to withdraw. Please let the researcher know whether or not you are happy for the data that has been collected up to this point to still be used. You are completely free to ask for any data to also be removed should you wish it to be, if the data is not anonymised. When data is anonymised, it means personal data relating to it has been permanently removed, so the researcher will not know which belongs to you. You do not have to answer any questionnaire or interview questions you do not wish to.

25. **Whether there are any special precautions you must take before, during or after taking part in the study**

As outlined above and explained at the pre-screening assessment, you will be required to consume the provided standardised meals across the duration of the study. Participants will be required to refrain from physical activity and alcohol consumption 24 hours before each study visit too. You will also need to overnight fast (10 hours), consuming only water (up to 500 mL) before arrival for testing and avoid the consumption of any stimulants or protein formulas which may conflict with the study parameters (e.g. caffeine, energy drinks or whey protein shakes). If your health status changes, or you start taking medication, or other supplements during the time of the study, please let us know asap.

Two servings of either the test or control product will be consumed after exercise on the following days - acute muscle fatigue exercise protocol day, two consecutive recovery days following acute muscle fatigue exercise protocol. The first serving will be consumed immediately after exercise and the second serving will be consumed in the afternoon between two meals (~2.5 hours apart from each meal). Intake of the servings on subsequent recovery days will be at the same times as on the exercise day.

26. **Will I pass onto anyone else what you have told me?**

Your data will not be passed on to anybody internal or external that is not listed above. The only people who will be able to access the data, will be the principal investigator (Dr Ash Willmott) and members of the immediate research team, Addenbrookes Hospital Core Biochemical Assay Laboratory (for blood analysis) and Danone Global Research & Innovation Center, in the Netherlands. All data will be stored on a password protected hard drive.

27. **Summary of research findings**

A summary of the research findings will be available and can be provided to you, if you wish, following the completion of the study. This can be arranged after the completion of the study. The summary of research findings can be sent to you via email if you would like to provide these contact details.

28. **Contact details for complaints**

If you have any complaints about the study, please contact ash.willmott@aru.ac.uk in the first instance. There are also, however, details about ARU's complaints procedure should you wish to use it. Email address: complaints@aru.ac.uk. Postal address: Office of the Secretary and Clerk, Anglia Ruskin University, Bishop Hall Lane, Chelmsford, Essex, CM1 1SQ.

Version control = Date 01.5.25 V4

PARTICIPANT CONSENT FORM

NAME OF PARTICIPANT:

Title of the project: BOLT STUDY Part B: The effects of commercially available high protein drink on recovery from muscle fatiguing exercise in 18-45-year-old male and female participants

Main investigator and contact details: Dr Ash Willmott (ash.willmott@aru.ac.uk)

Members of the research team: Dr Sanjoy Deb, Mr Dirk Dugdale,

1. I agree to take part in the above research. I have read the Participant Information Sheet (**Date 01.5.25 V4**) for the study. I understand what my role will be in this research, and all my questions have been answered to my satisfaction.

2. I understand that I am free to withdraw from the research at any time, without giving a reason. To do this I understand I can use the withdrawal slip below or email the main investigator.

3. I understand I am free to ask any questions at any time before and during the study.

4. I understand what information will be collected from me for the study

5. I understand what will happen to the data collected from me for the research. All blood samples will be collected, analysed and disposed of in accordance with the Human Tissue Act.

6. For the purposes of the General Data Protection Regulation (2018), if this project requires me to produce personal data, I have read and understood how Anglia Ruskin University will process it.

7. I have been told about any disadvantages or risks regarding me taking part.

8. I have been informed how my data will be processed, how long it will be kept and when it will destroyed.

9. I have been provided with a copy of this form and the Participant Information Sheet (**Date 01.5.25 V4**)

Name of participant (print)……

Signed……..….

Date……

I WISH TO WITHDRAW FROM THIS STUDY.

Title of the project: BOLT STUDY Part B: The effects of commercially available high protein drink on recovery from muscle fatiguing exercise in 18-45-year-old male and female participants.

If you wish to withdraw from the research, please speak to the researcher or email them Dr Ash Willmott - ash.willmott@aru.ac.uk, stating the title of the research or send them this withdrawal slip.

You do not have to give a reason for why you would like to withdraw.

Date 01.5.25 V4