ST. VINCENT'S UNIVERSITY HOSPITAL
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DEPARTMENT OF GASTROENTEROLOGY, ST VINCENT'S UNIVERSITY HOSPITAL GROUP

PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Study to assess the effects of UL-2-132 a food supplement on intestinal microbial diversity and quality of life in patients with dysbiosis in an inflammatory bowel disease cohort

NAME OF PRINCIPAL INVESTIGATOR: Dr Glen Doherty

You are being invited to participate in a research study. Thank you for taking time to read this consent form.

PARTICIPANT INFORMED CONSENT FORM

WHAT IS THE PURPOSE OF THIS STUDY?

The gut flora, also known as the 'microbiota', comprises of millions of different bacteria that live within the gastrointestinal tract. From previous studies, we know that there are 'good bacteria' that assist with well-being and 'bad bacteria' which can be associated with ill-health. The balance of these bacteria in each person can be influenced by many things including environment, diet, antibiotics and disease.

The aim of the study is to better understand whether dietary supplements, such as milk proteins, could be useful restore normal gut bacteria levels, improve how leaky the gut is, and improve well-being in patients with an imbalanced gut flora, also known as 'dysbiosis'. Patients with inflammatory bowel disease (IBD) are predisposed to developing an imbalanced gut flora due to inflammation and infections of the gastrointestinal tract along with possible increased use of antibiotics.

Previous research has shown the protein supplement, UL-2-132, has positive effects by restoring a normal gut flora balance. The protein supplement is derived from milk and is manufactured in a commercial dairy processing plant. It has passed all necessary safety controls prior to release for use by the centre.

St. Vincent's Healthcare Group Board of Directors: Chairman: Mr. James Menton, Dr. David Brophy, Mr. John Compton, Mr. Gerard Flood, Prof. Michael Keane, Mr. Myles Lee, Ms. Sharen McCabe, Prof. Patrick Murray, Mr. Frank O'Riordan, Mr. William Shannon.

Registered in Dublin, Ireland. Company Registration No: 338585. CHY No: 14187.
Registered Office: Elm Park, Dublin 4.

WHY HAVE I BEEN CHOSEN?

You have been chosen because you have a diagnosis of inflammatory bowel disease which is currently not active, and you attend clinic in the centre for colorectal disease.

WHAT WILL HAPPEN IF I VOLUNTEER?

Your participation is entirely voluntary. If you initially decide to take part, you can subsequently change your mind without difficulty. This will not affect your future treatment in any way. Furthermore, your doctor may decide to withdraw you from this study if he/she feels it is in your best interest.

A telephone screening visit will be performed to discuss the study and questions you may have. At this time, we will perform a brief interview to confirm you are a suitable candidate for the study.

If you agree to participate, you will be asked to sign and date this informed consent form, and you will be given a copy to keep. You will then be randomly assigned to one of two groups. Group one will be given a protein supplement, UL-2-132, for a total of 6 weeks. Group two will be given a placebo or 'dummy' supplement for a total of 6 weeks. The 'dummy' supplement will be an identical sachet containing microcrystalline cellulose which is a plant fibre. As part of this study, you will have 2 face-to-face consultations with a member of our research team over the period of 12-16 weeks. The final follow-up assessment at 12-16 weeks can be facilitated in person or by telephone and post.

The first visit will be scheduled just before you start the supplement and the second visit will be scheduled just after you complete the course, 6 weeks later. At the first visit, you will be randomly allocated to either take a protein supplement or placebo 'dummy' supplement. Neither you or any members of the research team will be informed of which supplement you have been given until completion of the study. You will have a 1 out of 2 chance (50%) to receive the supplement and a 1 out of 2 chance (50%) to receive the placebo. We will record your age, height, weight and sex. We will document the type of IBD you have and how long you have had it.

At each of these visits, you will be asked to donate a blood sample of approximately 50mls (3 tablespoons). This will be similar to a routine blood test you would have done in your GP practice. These blood tests will be reviewed in real time, meaning if there is any indication of a disease flare or activity, you and your medical team will be informed of the results. You will be offered the same medical care, irrespective of your involvement in the study. You will also be asked to submit a stool sample. This sample can be produced at home the day before with a home kit and brought into hospital on the day of your consultation. We will record your regular medications. You will be asked about recent symptoms of your IBD, any use of antibiotic/probiotics, any reaction to the supplements or deterioration to your health. You will also be asked to perform a grip strength test. This involves a hand-held device that measure the strength of the hand grip.

You will be asked to fill out 4 questionnaires that measure quality of life and complete an online dietary tool. It will take approximately 5-10 minutes to complete the 4 questionnaires. The dietary tool, FoodBook24, comprises of 3 x 24 hr diet recalls (2 weekday, 1 weekend day) on the first week and last week of the intervention (week 0 and week 6).

In between these 2 consultations, you will be contacted by telephone by one of the research team to monitor of new symptoms, patient concerns or problems that may have arisen.

Following completion of the supplement course, you will have another consultation which can either be by telephone and post or a face-to-face visit which will occur between 12-16 weeks from the beginning of the study. At this consultation, you will be asked to submit another stool sample and complete the health-related questionnaire previously completed.

ARE THERE ANY BENEFITS FROM MY PARTICIPATION?

As this is not a treatment for inflammatory bowel disease, we do not anticipate an effect on the natural course of your inflammatory bowel disease. The main objective of this study is to see if the bacterial profile of the gut can be normalised to a healthier balance. Half of patients recruited will be given a placebo 'dummy supplement'. In this case, we do not anticipate any direct benefits from your participation. Patients will also be given feedback from their dietary log submissions which may be of personal benefit.

ARE THERE ANY RISKS INVOLVED IN PARTICIPATING?

There are some small risks associated with taking part in this study.

While this is not a drug, there is a risk you may develop an allergy or reaction to the protein supplement, as with any type of food supplement.

When you have a blood sample taken as part of the study, there is a small risk of pain and/or bruising at site of the blood sample. For this reason, we will try to ensure blood samples are taken all at the same time so that there is no extra risk or discomfort from donating blood.

<u>COSTS AND REIMBURSEMENT</u>

WHAT HAPPENS IF I DO NOT AGREE TO PARTICIPATE?

If you decide not to participate in this study your treatment will not be affected in any way.

CONFIDENTIALITY

Your identity will be coded and pseudo-anonymised to ensure confidentiality at all times. A study number or "code" will identify you and all samples and results will be stored under this number. Pseudo-anonymised information means that your identity can be known by persons who hold the patients name, date of birth and hospital number and the corresponding code. This information will be stored in a secure area in a computer within the hospital. Any information shared outside of this office will only be in the form of coded, unidentifiable data. Your name will not be published or disclosed to anyone. The hospital records will be accessed from time to time to check how you are doing and to see which treatments you have received (medication, operations), and this information will again only be recorded against your study number. Coded samples will be sent to laboratories at approved collaborating universities including UCD, DCU and Teagasc for detailed analyses not

available in the local laboratory. These samples will all be coded and will not contain any patient identifiers. At any time, you can decide to request that all samples and results relating to you be destroyed and your continued care in the hospital will be entirely unaffected.

COMPENSATION

Your doctors are adequately insured by virtue of their participation in the clinical indemnity scheme and do not receive payment for your participation in the study.

WHO IS ORGANISING AND FUNDING THIS RESEARCH?

This study is organised and funded by the Food Health Ireland and the results will be made available, in time, on our website (www.colorectal.ie). Food for Health Ireland (FHI) is a technology centre that was established in 2008 and brings together leaders in the food industry and academia to improve global health through innovation in food.

You will not be paid for taking part in this study, but you should not experience any additional expenses as a result of taking part.

HAS THIS STUDY BEEN REVIEWED BY AN ETHICS COMMITTEE?

The St. Vincent's Healthcare Group, Ethics and Medical Research Committee have reviewed and approved this study.

CONTACT DETAILS

If you have any questions about the study please contact; Dr Glen Doherty/Ms Annie Coe Tel - 221 4711 Bleep 561

CONFIDENTIALITY & DATA PROTECTION

1. IDENTITY OF THE CONTROLLER OF PERSONAL INFORMATION

1.	**SVUH – Facility Provider for patients and clinical care** **Company Type: PLC,** **Company Registration number – 338585** **Having its registered office at:** **SVUH, Elm Park, Dublin 4**
2.	**Professor Glen Doherty – Principal Investigator and clinical care** **Company Type: SVUH Employee,**

	Company Registration number – NA **Having its registered office at:** **SVUH, Elm Park, Dublin 4**

Pharmaceutical company, CRO, other health agency, other universities is an independent data controller in the following circumstances:

2. CONTACT DETAILS OF THE DATA PROTECTION OFFICER

2.1

The data protection officer for SVUH and PI is:

Orlaith McCarthy, SVUH, Elm Park, Dublin 4, Contact 01 221 3541

Email: dataprotection@svuh.ie

3. PROCESSING OF YOUR PERSONAL DATA

St Vincent's University Hospital will process your personal data for the following purposes on the basis of your consent:

Personal data	Purpose of processing
1. Identification e.g. name, address, DOB (please note this and subsequent information will be anonymised/coded once leaving SVUH)	(a)Originally captured as part of medical care (b) used for purpose of carrying out research
2. Test results	Clinical care, safety measures, research outcomes
3. Clinical History (not identifiable)	PMH relevant to study outcomes
4. Interviews	Assess patient GI health pre/post treatment
5. Questionnaires	PROMS required to measure response to treatment

3.1 Where does St. Vincent's University Hospital obtain my personal data from?

Most of the personal data we process is obtained from you directly but we also obtain personal data about you from your

- medical notes,
- lab test results,

4. SHARING OF PERSONAL DATA

Person/Company/institute	Requirement for sharing
N/A Personal Data will not be shared with personnel outside the research team	

4.1 Service Providers

We use third party service providers who provide services including financial services, occupational health and IT services. In providing the services, your personal data will, where applicable, be processed by the service provider on our behalf.

We will check any third party that we use to ensure that they can provide sufficient guarantees regarding the confidentiality and security of your personal data. We will have written contracts with them which provide assurances regarding the protections that they will give to your personal data and their compliance with our data security standards and international transfer restrictions.

4.2 Disclosures to Third Parties

In certain circumstances, we share and/or are obliged to share your personal data with third parties outside St. Vincent's Hospital, for the purposes described above and in accordance with Data Protection Legislation.

These third parties include but are not limited to:

- the Health Products Regulatory Authority;
- the Health Service Executive;
- the Joint Commission International;
- relevant industry bodies;
- external professional advisors; and
- others, where it is permitted by law, or where we have your consent.

5. TRANSFERS OUTSIDE THE EUROPEAN ECONOMIC AREA

We will not transfer, store or process your personal data outside the European Economic Area.

5.1 If you would like to see a copy of any relevant provisions, please contact your data protection officer (see "Contact Us" section below).

6. HOW IS MY PERSONAL DATA SECURED

6.1 St. Vincent's University Hospital operates and uses appropriate technical and physical security measures to protect your personal data.

6.2 We have in particular taken appropriate security measures to protect your personal data from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access, in connection with this research study. Access is only granted on a need-to-know basis to those people whose roles require them to process your personal data. In addition, our service providers are also selected carefully and required to use appropriate protective measures.

7. STORAGE OF PERSONAL DATA

We will keep your personal data for 10 years. This may mean that some information is held for longer than other information.

8. YOUR RIGHTS

8.1 You may have various rights under Data Protection Legislation. However, in certain circumstances, these rights may be restricted[1]. In particular, your rights may be restricted where this is necessary: (i) for the prevention, detection, investigation and prosecution of criminal offences; (ii) in contemplation of or for the establishment, exercise or defence of a legal claim or legal proceedings (whether before a court, tribunal, statutory body or an administrative or out-of-court procedure); and/or (iii) for the performance of a task carried out in the public interest or in the exercise of official authority vested in St. Vincent's University Hospital.

These rights may include (as relevant):

(i) **The right of access** enables you to check what type of personal data we hold about you and what we do with that personal data and to receive a copy of this personal data;

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[1] *Article 23 of the General Data Protection Regulation, which is transposed into Irish law by section 59 of the Data Protection Act 2018, sets out the circumstances in which your rights may be restricted.*

(ii) **The right to object** to processing of your personal data where that processing is carried out on the basis of our legitimate interests. We will stop using your personal data unless we can demonstrate an overriding legitimate ground for the continued processing of this personal data;

(iii) **The right to rectification** enables you to correct any inaccurate or incomplete personal data that we hold about you;

(iv) **The right to erasure** enables you to request that we erase personal data held about you in certain circumstances;

(v) **The right to restrict processing** of your personal data by us in certain cases, including if you believe that the personal data held about you is inaccurate or our use of the personal data is unlawful; and

(vi) **The right to data portability** enables you to receive your personal data in a structured, commonly used and machine readable format and to have that personal data transmitted to another data controller

9. YOUR RIGHT TO LODGE A COMPLAINT WITH A SUPERVISORY AUTHORITY

9.1 Without prejudice to any other administrative or judicial remedy you might have, you may have the right under data protection legislation in your country (where applicable) to lodge a complaint with the relevant data protection supervisory authority in your country (i.e. the Office of the Data Protection Commissioner in Ireland) if you consider that we have infringed applicable data protection legislation when processing your personal data. This means the country where you are habitually resident, where you work or where the alleged infringement took place.

10. CHANGES TO THIS INFORMATION

10.1 We may decide to make changes to this Participant Information and Consent Form. If a change is made, we will notify you in person of such changes. An updated Participant Information and Consent Form will be provided to you in advance of any change actually taking effect.

11. CONTACT US

11.1 For further information or if you have any questions or queries about this Participant Information and Consent Form, please contact:

By letter:	Orlaith McCarthy**,** Data Protection Officer, St Vincent's University Hospital Elm Park, Dublin 4
By email:	dataprotection@st-vincents.ie
By telephone:	(01) 221 3591

CONSENT FORM

PLEASE TICK YOUR RESPONSE IN THE APPROPRIATE BOX

- I have read and understood the Participant Information and Consent Form YES ☐ NO ☐
- I have had the opportunity to ask questions and discuss the study YES ☐ NO ☐
- I have received satisfactory answers to all my questions YES ☐ NO ☐
- I have received enough information about this study YES ☐ NO ☐
- I understand that I am free to withdraw from the study at any time without giving a reason and without this affecting my future medical care YES ☐ NO ☐
- I agree that the samples I have given and the information gathered about me can be coded and stored in the Education & Research Centre, St. Vincent's University Hospital for use in future projects relating to bowel diseases without further consent being required and subject to the research being approved by a Research Ethics Committee. I understand that some of these projects may be carried out by researchers in SVHG and affiliated universities under the direction of the Principal Investigator listed above. YES ☐ NO ☐
- I am aware of the potential risks, benefits and alternatives of this research study. YES ☐ NO ☐
- I consent to take part in this research study having been fully informed of the risks, benefits and alternatives. YES ☐ NO ☐
- I give informed consent to have my data processed as part of this research study. YES ☐ NO ☐

STORAGE & FUTURE USE OF INFORMATION:

- I give permission for material/data to be stored for possible future research related to the current study without further consent being required but only if the research is approved by a Research Ethics Committee. YES ☐ NO ☐
- I agree that some future research projects may be carried out by researchers in UCD, RCSI, DCU, Teagasc Food Research Centre and Trinity College Dublin. YES ☐ NO ☐
- I understand I will not be entitled to a share of any profits that may arise from the future use of my material/data or products derived from it. YES ☐ NO ☐

Participant's Signature: _____
Date: _____
Participant's Name (block capitals): _____

Investigator's Signature: _____
Date: _____
Investigator's Name (block capitals): _____

Translator's Signature: _____
Date: _____
Translator's Name (block capitals): _____

Legal Rep./Guardian's Signature: _____
Date: _____
Legal Rep./Guardian's Name (block capitals): _____