INFORMED CONSENT FORM Version: 1.0, Date: Apr 27, 2021					PARTICIPANT INITIALS									
SCREENING NO.					DATE: (MMM/DD/ YYYY)	M	M	M	D	D	Y	Y	Y	Y

Protocol Title: A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of *L. plantarum* UALp-05™ in diarrhea-predominant-irritable bowel syndrome.

Protocol ID: **UAS/201003/LPLANTARUMUALP05/IBS**

Protocol Version: 1.0

Date: Apr23, 2021

Name of the participant: _____ _____ _____

(First) *(Middle)* *(Last)*

Date of Birth: D D | M M M | Y Y Y Y

(Date) *(Month)* *(Year)*

(For example, if date of birth is 01/01/2000 then write 01 Jan 2000)

Telephone no: | | | | | | | | | | |

Address: _____

_____

Important Note: Participant's Personal Details are to be captured from ID Proof

Qualification: _____

Occupation:

- Student ☐
- Self – Employed ☐ ***(Please tick as appropriate)***
- Service ☐
- Others ☐ _____

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SCREENING NO.					DATE: (MMM/DD/ YYYY)	M	M	M	D	D	Y	Y	Y	Y

Annual Income: _____

Name of the Nominee: _____ _____ _____

(First) *(Middle)* *(Last)*

Address: _____

_____

Relation to the Participant: _____ **Telephone no:** _____

DECLARATION BY THE PARTICIPANT

Sr. No.	Declaration	Participant's Initials
I.	I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions.	[ ]
II.	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	[ ]
III.	I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I	[ ]

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	understand that my identity will not be revealed in any information released to third parties or published.	
IV.	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).	[ ]
V.	I agree to take part in the above study	[ ]
VI.	I understand that neither the current Investigational Product nor participation in the current study can cause COVID. In case, during the course of study, if I get infected with COVID, we will be withdrawn from study and neither sponsor nor CRO is liable for any damage.	[ ]

AWARENESS INSTRUCTIONS FOR CORONAVIRUS DISEASE (COVID-19)

Participant Screening Number					Date of Providing Information	M	M	M	D	D	Y	Y	Y	Y

1. INTRODUCTION

Coronavirus disease (COVID-19) is an infectious disease caused by a new virus. The disease causes respiratory illness (like the flu) with symptoms such as a cough, fever, and in more severe cases, difficulty breathing.

You can protect yourself by washing your hands frequently, avoiding touching your face, and avoiding close contact (1 meter or 3 feet) with people who are unwell.

2. HOW IT SPREADS

Coronavirus disease spreads primarily through contact with an infected person when they cough or sneeze. It also spreads when a person touches a surface or object that has the virus on it, then touches their eyes, nose, or mouth.

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People may be sick with the virus for 1 to 14 days before developing symptoms. The most common symptoms of coronavirus disease (COVID-19) are fever, tiredness, and dry cough. Most people (about 80%) recover from the disease without needing special treatment.

More rarely, the disease can be serious and even fatal. Older people, and people with other medical conditions (such as asthma, diabetes, or heart disease), may be more vulnerable to becoming severely ill.

3. SYMPTOMS:

Cough, Fever, Tiredness, and Difficulty breathing (severe cases)

4. HOW TO PREVENT

a. Wash your hands frequently

Regularly and thoroughly clean your hands with an alcohol-based hand rub or wash them with soap and water.

Why? Washing your hands with soap and water or using alcohol-based hand rub kills viruses that may be on your hands.

b. Maintain social distancing

Maintain at least 1 meter (3 feet) distance between yourself and anyone who is coughing or sneezing.

Why? When someone coughs or sneezes they spray small liquid droplets from their nose or mouth which may contain virus. If you are too close, you can breathe in the droplets, including the COVID-19 virus if the person coughing has the disease.

c. Avoid touching eyes, nose and mouth

Why? Hands touch many surfaces and can pick up viruses. Once contaminated, hands can transfer the virus to your eyes, nose or mouth. From there, the virus can enter your body and can make you sick.

d. Practice respiratory hygiene

Make sure you, and the people around you, follow good respiratory hygiene. This means covering your mouth and nose with your bent elbow or tissue when you cough or sneeze. Then dispose of the used tissue immediately.

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Why? Droplets spread virus. By following good respiratory hygiene you protect the people around you from viruses such as cold, flu and COVID-19.

e. If you have fever, cough and difficulty breathing, seek medical care early

Stay home if you feel unwell. If you have a fever, cough and difficulty breathing, seek medical attention and call in advance. Follow the directions of your local health authority.

Why? National and local authorities will have the most up to date information on the situation in your area. Calling in advance will allow your health care provider to quickly direct you to the right health facility. This will also protect you and help prevent spread of viruses and other infections.

f. Stay informed and follow advice given by your healthcare provider

Stay informed on the latest developments about COVID-19. Follow advice given by your healthcare provider, your national and local public health authority or your employer on how to protect yourself and others from COVID-19.

Why? National and local authorities will have the most up to date information on whether COVID-19 is spreading in your area. They are best placed to advise on what people in your area should be doing to protect themselves.

If you need any additional information or have any doubts please ask us or consult your family physician. Do not hide any medical information.

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Queries asked by the participant.	Resolution to the query provided by the investigator.

Sr. No.	Name		Signature	Date
01	Name of the Participant			
02	Name of the Investigator			
Note	Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the participant			

INFORMED CONSENT DOCUMENT- **PATIENT INFORMATION SHEET (PIS)** **Version: 1.0, Date: Apr 27, 2021**	**PARTICIPANT INITIALS**									
	SCREENING NO.									
Protocol ID:UAS/201003/LPLANTARUMUALP05/IBS	**DATE (MMM/DD/YYYY)**	M	M	M	D	D	Y	Y	Y	Y

This information sheet gives detailed information about the research study on Irritable Bowel Syndrome (Diarrhea Predominant). I am going to give you information and invite you to be part of this research. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have any questions later, you can ask me or any other study staff.

You can take time to decide whether or not you will participate in this study. Before you decide you can talk to your relatives and friends about this study. If you wish to participate in the study you will be asked to sign the consent form. You will receive a signed and dated copy of the Informed Consent Form.

Protocol Title	A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of *L. plantarum* UALp-05™ in diarrhea-predominant-irritable bowel syndrome
Sponsor	Chr. Hansen A/S Bøge Allé 10-12 DK-2970 Hørsholm
Contact person from sponsor	Christopher Martoni
Contract Research Organization	**Vedic Lifesciences Private Limited** 118, Morya House, Off New Link Road, Andheri (West), Mumbai-400 053. Tel: 91 22 4217 2324
Contact Person from CRO	Dr. Sonal Raote
Independent Ethics Committee (IEC)	Harmony Ethical Research Committee Shree Hospital Kavan 70M (Central Avenue), Ambedkar Garden 19th Rd M. S. D. Marg, Chembur, Mumbai, Mumbai City Maharashtra
Contact person from IEC	Ms. Vidula Shevde

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Q1. What is the purpose of the study?

The primary objective is to evaluate the effect of IP consumption on Participant's global assessment of IBS symptoms, as assessed by change in IBS-Symptom Severity Scale (IBS-SSS) total score.

Q2. What is the study duration?

Total duration of the study is 8 weeks (56 days) excluding the screening and run-in period.

Q3. Why am I being selected? How many participants are involved?

You are selected to participate in this study because you are diagnosed with Diarrhea-Predominant Irritable bowel syndrome (IBS-D) as per Rome IV IBS criteria.

You will be one of the 360 participants who will be participating in this study.

Q4. What is the Investigational Product? (Test Product)

L.plantarum UALp-05™ is a probiotic for IBS-D. It is expected that the probiotic capsules benefit research participants by reducing overall symptoms related to IBS-D. In this study two doses of L.plantarum UALp-05™, 1 billion CFU/capsule and 10 billion CFU/capsule will be evaluated to observe the effects.

Q5. What is placebo?

Placebo is a dummy capsule which looks similar to Investigational product capsule in size, shape and color but has no effect on IBS-D. Hence you will not be having any change on symptoms of IBS-D if you are on placebo arm.

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Q6. How will the study medication be allotted to me?

If you agree to participate in this study and are found to be eligible to do so, you will receive either L.plantarum UALp-05™ (L.plantarum UALp-05™ NLT 1 billion CFU/capsule or L.plantarum UALp-05™ NLT 10 billion CFU/capsule) or placebo as per the randomization chart generated by the computer. You will have an equal chance to get either one of the two groups of L.plantarum UALp-05™ or Placebo.

Regimen: One capsule to be taken orally before a meal with a glass of water. The time of IP consumption should preferably be consistent throughout the study period.

Q7. What are the visit specific procedures carried out for the study?

Screening visit: The designated person at the study site will thoroughly explain you the entire study design in your local language following which a written, signed and dated informed consent to participate in the study will be obtained from you. By signing this form, you authorize us to use your study related data for analysis or further research purposes. Also, a separate consent will be sought about providing a stool sample at two time-points (Day 0 and Day 56) in this study. The study participation consent from you will be mandatory and will help us to proceed with further study activities. You will be provided a copy of a signed informed consent form. You will be assessed for eligibility criteria to participate in the study. The designated person will assess your weight to height ratio for BMI. Study doctor will assess medical history, blood pressure (BP) and Pulse rate (PR). Your general body check-up will be conducted. UPT will be done to rule out pregnancy in females belonging to the reproductive age group. You will be advised to get tests done for FBG, HB and TSH. The Study Coordinator will record your diet in general .You will be instructed to continue with the same diet regime throughout the study period. APS-NRS (Abdominal Pain Severity Numerical Rating Score) will be obtained from you. You will be dispensed with run-in medication, stool sample collection kit and diet recall chart. You will be advised to submit your weekly response related to pain and other IBS symptoms on digital platform. If you satisfy all the eligibility criteria including laboratory

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evaluation, only then you will be
eligible for next visit. In case of any untoward medical condition please feel free to contact the study doctor either telephonically or by email. If not then you can also inform the doctor on the day of your visit.

Day 0: On this day you will have to visit the study site if you fit into the study as per protocol. Stool sample will be collected by lab personnel in morning. The study doctor will conduct physical examination, record medical history. The date of LMP will be asked in case of female participants and if required UPT will be done to rule out pregnancy in females. Run-in medication and diet recall chart will be reconciled and compliance for same will be checked. IBS-SSS (Irritable bowel syndrome Severity Scoring system) will be obtained from you. You will be instructed to provide your response on BSS, IBS-QOL, IBS-PSS, APS-NRS. You will be instructed to record your diet of three days, 10 days prior to the next visit. These 3 days should include a weekend day. You will be dispensed with study medication and weekly diaries (including questionnaire i.e BSS, IBS-QOL, IBS-PSS, APS-NRS) Participants will be instructed to fill paper based response in case of internet or technical issues. Adverse events will be monitored in each visit.

Day 28: On this day you will have to visit study site for follow up. The study doctor will conduct physical examination, record medical history. Please inform the study doctor in case of any untoward medical condition. The date of LMP will be asked in case of female participants and if required UPT will be done to rule out pregnancy in female. IBS-SSS (Irritable bowel syndrome Severity Scoring system) will be obtained from you. You will be instructed to provide your response on BSS, IBS-QOL, IBS-PSS, APS-NRS same as randomization visit. Reconciliation of study medication and diet recall chart will be done. Then you will be dispensed with study medications and weekly diaries (including questionnaire i.e

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BSS, IBS-QOL, IBS-PSS, APS-NRS) Participants will be instructed to fill paper based response in case of internet or technical issues. Adverse events will be monitored in each visit. You will have to continue recording your diet in the calorie counting application and fill details of your diet consumed 3 days, 10 days prior to the next visit. These 3 days must include a weekend day.

Day 56: On this day you will have to visit the study site. The study doctor will conduct physical examination, record medical history. Please inform the study doctor in case of any untoward medical condition. The date of LMP will be asked in case of female participants and if required UPT will be done to rule out pregnancy in female. IBS-SSS (Irritable bowel syndrome Severity Scoring system) will be obtained from you along with that you .You will be instructed to provide your response on BSS, IBS-QOL, IBS-PSS, APS-NRS. Reconciliation of study medication and diet recall chart will be done. Adverse events will be monitored. On this day stool samples will be collected by lab from willing participants.

Q8. What are my responsibilities related to the study?

You will have to come to site for all the scheduled visits within stipulated timelines. You will have to take the study product provided to you as per the instructions given. You will be expected to fill the diary on the scheduled dates and thereafter send it to the study team. You are not allowed to take any other medication except the study product without consulting the study doctor.

Q9. What is dietary recall?

It is a dietary assessment tool that provides a clear picture of how many calories you have consumed during the day through food and drink. It is done by a calorie counter, an easy to use application on a paper based diet recall chart in which the participants will have to fill details

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of diet consumed in 3 days, 10 days prior to the next visit. These 3 days should include a weekend day. The responses from same will be reconciled by study coordinator on digital app.

Q10. What are the foreseeable risks or inconveniences for me in the study?

L.plantarum UALp-05™ has already been evaluated for its safety and efficacy in previous studies on human beings. It has already been marketed without any safety concerns.
However, you are advised to inform the doctor in case you experience any sense of discomfort. You will also be provided with contact details of study doctors who can be contacted in case of emergency.

Q11. What are the possible benefits of participating in the study?

You may or may not benefit by participating in the study. The study product may benefit you by improving your health. More importantly you will have the opportunity to contribute to research, the result of which will benefit mankind.

Q12. What are the alternative available treatments?

If you decide not to take part in this study, your treating physician will provide you with required treatment based on your health condition. Your decision to participate in the study will not influence your further treatment plan.

Q13. Is there any compensation and/or treatment available for me in the event of study related injury?

You will not receive any direct compensation for participating in this study. However, the study medication for the entire study duration will be provided to you free of cost. All laboratory investigations will be done free of cost. In case of side effects due to the study

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medication, relevant treatment to overcome the side effect will be provided to you as long as required, at no cost. You are covered under an insurance policy for any side-effects related to study.

However, you will not receive any compensation for any injury or medical condition caused during or after completion of the study, which is not related to study product or study procedure. You will be reimbursed for your time and travel expenses to the clinic at the end of study.

Q15. What about the information of changes that occur in the study during the course of the study?

You will be notified in a timely manner if any new findings related to safety and efficacy of the product develops during the study and deemed to affect your willingness to continue in the study. An additional declaration/ consent will be obtained for the same.

Q16. What are the circumstances/ reasons under which I can be terminated from the study?

Your doctor or sponsor may withdraw you from the study without your consent for your safety in case you have a side effect from the study product, in case you need treatment/ Intervention which is prohibited in the study or if you are non-compliant to the study procedures and product.

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Q17. Whom should I contact in case of emergency?

In case of any problems related to study or any other medical emergencies, you should contact the doctor immediately at the given number below.

Name of Study Doctor	
Address	
Contact Number	