Participant Study ID: _____

CONSENT FORM

A Proof-of-Concept Study to Assess the Efficacy of Symprove Probiotics in Managing Persistent Gastrointestinal Symptoms in Adult Coeliac Disease Patients in Histological Remission

Name of Researcher: [insert CI name]

Please initial box

1	I confirm that I have read and understood the information sheet ([insert version & date]) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2	I understand that my participation 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.	
3	I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records to make sure the research has been managed correctly.	
4	I understand that I will take Symprove (70ml daily) for 3 months and complete questionnaires about my symptoms and quality of life monthly during this period.	
5	I understand that taking Symprove may cause mild gastrointestinal discomfort initially, which typically resolves within a few days, and that this is a widely available food supplement with a good safety profile.	
6	I agree to provide stool samples as part of my involvement in this study at baseline (Month 0) and Month 3. I understand that these samples will be labelled with a study ID and not my name, and sent to a commercial Laboratory (in Europe) to be analysed for gut bacteria and then destroyed, and that I will not gain any direct personal or financial benefit from them.	
7	I agree to take part in the above study	
8	OPTIONAL: I agree that data collected for this study can be used for future research and may be shared anonymously with external researchers based worldwide, as detailed in the information sheet.	

Signatures:

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

Participant Contact Details:

Name:	
Address:	
Telephone:	
Email:	

Preferred method of contact for study updates:

☐ Email	☐ Post	☐ Telephone

Would you like to receive a summary of the study results when available?

☐ Yes	☐ No