

<TO BE PRINTED ON TRUST HEADED PAPER>



Optimisation before Crohn's surgery using Exclusive Enteral Nutrition (OCEaN) Study

Informed Consent Form

Including immunological sub-studies

Version 3.0b 12-FEB-2025

Site name:	
OCEaN Trial Number:	
Patient Initials:	
Principal Investigator:	

Please tick the box for each statement on the online form to confirm your consent

1	I confirm that I have read and understood the OCEaN participant information sheet, version number _ . _ dated __/__/____. I have had the opportunity to consider the information and ask questions, and these have been answered satisfactorily.	☐
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2	I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that even if I withdraw from the study, data collected up to the point of my withdrawal may still be used.	☐
3	I understand that relevant sections of my medical notes, and data collected during the study (including all of the information provided by me in both the study and diet/food related questionnaires) may be looked at by responsible individuals from the OCEaN research team, representatives of the sponsor, regulatory authorities, or my NHS Trust, where this is relevant to my taking part in this research. I give permission for these individuals to have direct access to my records.	☐
4	I have read (or had read to me) and understood the information in the Participant Information Sheet about what happens with my personal data collected for this study.	☐
5	I agree to my GP and other healthcare professionals involved in my care being informed of my participation in this study. They may be contacted to provide medical information on my history and progress in confidence.	☐
6	I understand and acknowledge that data collected that identifies me by name, on e.g. Informed consent forms, contact details form will be transferred from where it is collected and stored at the University of Birmingham where it will be held in confidence and stored securely in accordance with the University's Information Security and Management Policy. I give permission for the transfer and storage of this data.	☐
7	I agree for my stool samples (or part of my stool samples) to be sent to the University of Glasgow, University of Strathclyde and Czech University of Biological Sciences for the purpose of this research.	☐
8	I understand and acknowledge that data collected as part of the OCEaN study (including data that identifies me by name) will be shared with OCEaN researchers at the University of Glasgow, King's College London, the Earlham Institute, University of Strathclyde and Czech University of Biological Sciences for the purpose of this research.	☐



9	I understand that the information and samples collected will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results.	☐
10	I understand and agree that stool samples collected may be stored and used for chemical and DNA analysis as part of this and future ethically approved related studies and may be shared anonymously with other researchers.	☐
11	I understand that the information (data) collected about me may be used to support other ethically approved related research in the future, and may be shared anonymously with other researchers.	☐
12	I understand that the information held and maintained by NHS England together with current and future NHS bodies, may be used in the future to provide information about my long-term health status and healthcare. For this purpose, I agree to the University of Birmingham Clinical Trials Unit holding my name, gender, address, date of birth and NHS number.	☐
13	I accept that, in the unlikely event of the loss of my capacity, the research team will retain my personal data already collected and will continue to use this data for the sole purposes for which consent was sought.	☐
14	I agree to OCEaN study team sending me an online link to complete the questionnaires via the e-mail address or mobile number or paper questionnaires being sent to the postal address provided.	☐
15	I agree to take part in the OCEaN Study.	☐
Entry to the main trial <u>requires agreement to all statements above.</u>		
16	I would be happy to be contacted about participating in the qualitative interviews. I give permission to be contacted by a researcher from the OCEaN team about this research.	Yes ☐ No ☐
17	If I am allocated to the EEN (Liquid diet), I agree to my name and e-mail address being provided to a third party (FutureLearn Ltd), so that I am able to access the online support website, should I choose to.	Yes ☐ No ☐



18	I agree that my mobile number can be shared with a third-party SMS provider for the sole purpose of sending me text messages for trial specific questionnaires.	Yes ☐ No ☐
19	If applicable, I agree that should I become pregnant during the study, the study team will collect information about my pregnancy and its outcome. I understand that my permission to the collection of information about my pregnancy and its outcome is entirely voluntary for the OCEaN Trial and that I am free to withdraw this permission at any time, without giving any reason and without affecting the quality of my medical care or legal rights being affected.	Yes ☐ No ☐ N/A ☐
20	Optional immunological sub-study I agree to blood and tissue samples being sent for analysis at University of Birmingham and University of Glasgow laboratories and used for ethically approved research, both within this study and future related studies.	Yes ☐ No ☐
21	Thank you for agreeing to take part in the OCEaN Study, you will be provided with a copy of this consent form. Please select your preferred method of receiving the consent form: ☐ Electronic copy (via email) ☐ Printed copy (if consent not taken face to face this will be posted) Provide email address: 	

Participant's full name	Participant's signature	Please confirm the date you, the participant signed this form:									
		<table><tr><td>D</td><td>D</td><td>M</td><td>M</td><td>M</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table>	D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y			



If applicable:

Name of Witness	Signature of Witness	Please confirm date witness signed this form:									
		<table><tr><td>D</td><td>D</td><td>M</td><td>M</td><td>M</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table>	D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y			

Name of Person taking Consent	Signature of Person taking Consent	Please confirm date person taking consent signed this form:									
		<table><tr><td>D</td><td>D</td><td>M</td><td>M</td><td>M</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table>	D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y			
Contact Number:											
E-mail:											

THIS CONSENT FORM IS NOW COMPLETE

PARTICIPANT: Thank you for agreeing to take part in the **OCEaN** trial. If you have requested a printed copy of this informed consent form, the researcher will now provide you with a printed copy of this signed consent form for your records. If you requested to receive an electronic copy of this informed consent form, a copy will be sent to your e-mail address. You are advised to check your e-mail inbox for receipt of the form. If you do not receive a copy of this form via the e-mail address you provided, please speak to a member of the research team who would be happy to resolve this for you.

PERSON TAKING CONSENT: When completed, if requested, please provide the participant with a printed copy of the informed consent form. Please retain a copy in the participant's medical notes. A printed copy should be filed in the OCEaN Investigator Site File.

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