

&lt;TO BE PRINTED ON TRUST HEADED PAPER&gt;



## Optimisation before Crohn's surgery using Exclusive Enteral Nutrition (OCEaN) Sub-Study:

# Crohn's Optimisation And Surgical Timing (COAST)

## Informed Consent Form

Version 3.0 08-OCT-2024

Site name:	
OCEaN Trial Number:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Participant Initials:	<input type="text"/> <input type="text"/> <input type="text"/>
Principal Investigator name:	

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

1	<p>I confirm that I have read and understood the COAST Study participant information sheet, version number _ . _ dated __/___/____.</p> <p>I have had the opportunity to consider the information and ask questions, and these have been answered satisfactorily.</p>	<input type="checkbox"/>
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<b>2</b>	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.	<input type="checkbox"/>
<b>3</b>	I have read (or had read to me) and understood the information in the COAST Participant Information Sheet about what happens with my personal data collected for this study.	<input type="checkbox"/>
<b>4</b>	I understand that the information (data) 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.	<input type="checkbox"/>
<b>5</b>	I understand that the information (data) collected may be used to support other ethically approved related research in the future, and may be shared anonymously with other researchers.	<input type="checkbox"/>
<b>6</b>	I understand and acknowledge that data collected that identifies me by name, on e.g. Informed consent forms 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.	<input type="checkbox"/>
<b>7</b>	I understand and acknowledge that data collected as part of the COAST Study (including data that identifies me by name) will be shared with COAST researchers at King's College London for the purpose of this research.	<input type="checkbox"/>
<b>8</b>	I agree to the OCEaN study team sending me an online link to complete the COAST questionnaires via the e-mail address or mobile number, or paper questionnaires being sent to the postal address provided.	<input type="checkbox"/>



9	I agree to take part in the COAST Study.	<input type="checkbox"/>
Entry to COAST <u>requires agreement to all statements above.</u>		
10	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.	<b>Yes</b> <input type="radio"/> <b>No</b> <input type="radio"/>
11	<p>Thank you for agreeing to take part in the COAST Sub Study, you will be provided with a copy of this consent form. Please select your preferred method of receiving the consent form:</p> <p><input type="radio"/> Electronic copy (via email)</p> <p><input type="radio"/> Printed copy (if consent not taken face to face, this will be posted)</p> <p>Provide email address</p> <p>.....</p>	

Participant's full name	Participant's signature	Please confirm the date you, the participant signed this form:									
		<table border="1"> <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 border="1"> <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			

Researcher's full name	Researcher's signature	Please confirm date researcher signed this form:									
		<table border="1"> <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 Sub-Study: COAST**. 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 via the e-mail address you provided, please speak to a member of the research team who will be happy to resolve this for you.

**RESEARCHER:** 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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