Participant study ID: | | | | | | | |

Study Centre Name (i.e. Trust / Health Board name)

Study Site Name (i.e. Hospital name)

Participant study ID						

Complete Sections 1 & 2 of this CRF 7 days prior to the participant's scheduled follow up appointment to assess the participant's eligibility for follow up and fax to the Trial Office.

Complete Sections 3 to 11 after the participant's routine follow up appointment for their ulcerative colitis approximately 3m after their trial treatment. These sections refer to the time from the date of randomisation/discharge up to and including the date of their 3m follow up appointment.

- Once each page has been completed, the person completing it should initial and sign their name and record the date of completion at the bottom of that page.
- **Section 10** relates to blood ciclosporin levels and should **only** be completed if the participant was randomised to receive Sandimmun®.
- Any amendments to the CRF should be done by crossing out the error **once**, initialling and dating that action. The new entry should be written in alongside as clearly as possible.
- If you have any queries relating to the completion of this CRF, please contact the CONSTRUCT Helpdesk by email on CONSTRUCTHelpdesk@swansea.ac.uk

Initials of person completing this page:		Signature		**Date** page completed:	

Participant study ID: | | | | | | | |

Please complete 7 days before the participant's routine 3m follow up appointment with the healthcare professional is due.

Section 1: Participant demographics - update

Please check whether any of the following information about the participant has changed **since the date of discharge**.

- If there is no change to existing data, tick "No".
- If information about the participant has changed, tick "Yes" and record the new details.

Field	No	Yes	Change to…
Title			
Surname			
Address			
Postcode			
Tel number			
GP name			
GP practice			

- If any of this section of the CRF has been completed with a "Yes", please **detach it and fax it separately** to the CONSTRUCT Trial Office.
- Section 1 must be filed separately in a secure place.

Participant study ID: | | | | | | | |

Please complete 7 days before the participant's routine 3m follow up appointment with the healthcare professional is due.

Section 2: Patient eligibility for follow up

2a) Details of death of participant

Has the participant died since the **date of discharge**?

☐ No (**Go to Section 2b**)

☐ Yes *(Please record date of death and also complete an **AE Screening Form** for the event leading to the death)*

Date of death: | *d* | *d* | *m* | *m* | *y* | *y* | *y* | *y* |

2b) Details of withdrawal of participant

Has the participant withdrawn from any aspect of the trial **since the date of discharge**?

☐ No (**Go to Section 3**)

☐ Yes *(Complete a **Participant Withdrawal Form*** and also complete below*)*

Which of the following has the participant withdrawn from? (Instructions for completion of follow up data collection forms are in brackets)

☐ **Access to medical records AND completion of participant questionnaires**

(3m RCT CRF - UP TO DATE OF WITHDRAWAL. Do not send PFQ)

☐ **Access to medical records only**

(3m RCT CRF - UP TO DATE OF WITHDRAWAL. PFQ can be sent)

☐ **Completion of participant questionnaires only**

(3m RCT CRF – complete in full. Do not send PFQ)

☐ **Completion of trial treatment only**

(3m RCT CRF – complete in full. PFQ can be sent)

Participant study ID: | | | | | | | |

Complete Sections 3-10 as soon as possible after the participant's 3m follow up appointment with their healthcare professional as part of their ongoing care for their ulcerative colitis.

Please ensure that the information in this CRF corresponds to the information collected since the **date of the randomisation up to and including the date of the participant's 3m follow up appointment** with the PI / other authorised person.

All tests, etc done since the 3m follow up appointment will be collected in the 6m RCT CRF. To prevent double-counting, please ensure that the data in this CRF relates to information up to and including the 3m follow up appointment date but not beyond.

DATES FOR REFERENCE:															
Date of **randomisation**:								Date of **3m follow up** appointment:							
d	*d*	*m*	*m*	*y*	*y*	*y*	*y*	*d*	*d*	*m*	*m*	*y*	*y*	*y*	*y*

Section 3: Treatment continuation

Was the trial treatment discontinued prematurely **by the PI** (or other authorised person)?

- ☐ No (**Go to Section 4**)
- ☐ Yes *(Please complete the rest of **Section 3**)*

Date treatment discontinued: | d | d | m | m | y | y | y | y |

Reason for discontinuation:

- ☐ Adverse event occurred *(If so, also complete an **AE Screening Form**)*
- ☐ Surgery required *(If so, also complete an **AE Screening Form**)*
- ☐ Other *(please state)*

Participant study ID: | | | | | | | |

Section 4: Surgery details

Has the participant had **colitis-related** surgery since the **date of randomisation**?

☐ No **(Go to Section 5)**

☐ Yes (*Complete the rest of **Section 4** AND also complete an **AE Screening Form***)

Type of surgery	Date surgery performed	Tick if done as an emergency
Panproctocolectomy	d d m m y y y y	
Subtotal colectomy	d d m m y y y y	
Ileoanal pouch with stoma	d d m m y y y y	
Ileoanal pouch without stoma	d d m m y y y y	
Formation of ileostomy	d d m m y y y y	
A reversal procedure	d d m m y y y y	
Resuture procedure	d d m m y y y y	
Abscess drainage	d d m m y y y y	

Other colitis-related surgical procedure(s) *(please state what, the date it was performed and whether it was done as an emergency)*

_____ d d m m y y y y

Date of admission:	d d m m y y y y
Date of discharge:	d d m m y y y y

Participant study ID: | | | | | | | |

Section 5: Participant follow up events - New conditions

Please tick in the "Yes" or "No" column to indicate whether, according to the hospital notes, the participant has been diagnosed with any of the following **since they were randomised up to and including the date of the 3m follow up appointment** (include all diagnoses made during the 3m follow up appointment in this CRF).

The participant will be asked the same questions during their follow up appointment in the PFQ to capture all non-hospital diagnoses (e.g. GP diagnosis of a serious infection).

If "Yes" is ticked, record the site(s) of the condition and the date(s) of the diagnosis.

IMPORTANT: AN AE SCREENING FORM IS REQUIRED FOR EACH CONDITION.

Incidence of ….	No	Yes	Site(s) of condition	Date of diagnosis
Colorectal malignancies				d d m m y y y y
				d d m m y y y y
Other GI malignancies				d d m m y y y y
				d d m m y y y y
Non-GI malignancies				d d m m y y y y
				d d m m y y y y
Pneumonia				d d m m y y y y
				d d m m y y y y
Abscesses				d d m m y y y y
				d d m m y y y y
Other serious bacterial infections				d d m m y y y y
				d d m m y y y y
Renal disorders				d d m m y y y y
				d d m m y y y y

Please enter any additional sites and dates under the headings listed on the **Additional Comments Form** if there is insufficient space on this page.

Participant study ID: | | | | | | | |

For Section 6 onwards, please complete the data that relates to the study centre (i.e. the Trust / Health Board) where they were recruited, not just that particular hospital and include tests for any condition, not just their bowel condition.

Section 6: Healthcare contacts / episodes

Complete this section with **counts of the number of contacts / episodes** by the participant at the study centre (not just at the hospital where they were recruited).

Contact type (for any condition)	**Number of contacts**
1. Clinic visits (**Include** further Remicade® infusions (if relevant) and the 3m follow up appointment) since randomisation	
2. A&E attendances since randomisation	

Nights spent as an inpatient (for any condition)	**Number of nights**
1. Number of nights as an inpatient during the original episode that led to them being entered into the trial	
2. Number of nights as an inpatient since their discharge following their **first** infusion	

Participant study ID: | | | | | | | |

Section 7: Drugs given as an inpatient since randomisation

Complete the details of any drugs **given as an inpatient** since the ***date of randomisation to the date of the 3m follow up appointment***. Include any drugs given in response to an adverse event (AE) whilst an inpatient. Some common drugs have been listed for your convenience. Please write in any additional drugs not listed in the empty rows.

Drug name	Strength	Number per dose	Dose frequency	Number of days given (in total)	Used to treat an AE?
Adalimumab					
Azathioprine					
Mercaptopurine					
Methotrexate					
Prednisolone					
Septrin					

Participant study ID: | | | | | | | |

Section 8: Tests & procedures performed

Complete the **number of each test listed** performed at that **study centre** for **any condition** between **date of randomisation** and **date of 3m follow up appointment.**

INCLUDE all tests done as part of the 3m follow up appointment in this section.

Test type	N°. of tests / procedures performed
BLOOD TESTS	
1. Ciclosporin levels	
2. Full blood count	
3. C-Reactive Protein (CRP)	
4. Erythrocyte Sedimentation Rate (ESR)	
5. Urea & electrolytes	
6. Calcium & phosphate	
7. Liver function tests (LFTs)	
8. Clotting profile	
9. Thiopurine Methyltransferase (TPMT)	
PROCEDURES	
10. Oesophogastroduodenoscopy (OGD)	
11. Barium meal	
12. Barium follow through	
13. Barium enema	
14. Colonoscopy with biopsy	
15. Colonoscopy without biopsy	
16. Flexible sigmoidoscopy	
17. Rigid sigmoidoscopy	
18. CT scan	
19. MRI scan	
20. Abdominal x-ray	
21. Chest x-ray	
22. Stool culture/testing	

Participant study ID: | | | | | | | |

Section 9: 3m follow up appointment test results

Please record the results of the **tests done at the 3m follow up appointment with the healthcare professional**.

- Where tests use different units of measurement, please record the information as it is displayed locally, remembering to include local units of measurement
- Place a **cross** in the final column if the test has not been requested, either routinely or on this occasion.

9a – Clinical measurements at 3m follow up appointment

Measurement	Result		Test NOT requested (X)
Weight		*(Kg)*	
Pulse		*(bpm)*	
Temperature		*(ºC)*	
Systolic blood pressure		*(mm Hg)*	
Diastolic blood pressure		*(mm Hg)*	
Stool frequency		*(per day)*	
Bloody stool frequency		*(per day)*	

(Continued overleaf)

Participant study ID: | | | | | | | |

9b – Blood results at 3m follow up appointment

Measurement	Result		Test NOT requested (X)
Haemoglobin	_____	(*g/dL*)	
Urea	_____	(*mmol/L*)	
Creatinine	_____	(*mmol/L*)	
Sodium	_____	(*mmol/L*)	
Potassium	_____	(mmol/L)	
Chloride	_____	(mmol/L)	
Bicarbonate	_____	(mmol/L)	
C-Reactive protein (CRP)	_____	(mg/L)	
Erythrocyte Sedimentation Rate (ESR)	_____	(mm/hr)	
Alanine transaminase (ALT)	_____	(U/L)	
Aspartate transaminase (AST)	_____	(*U/L*)	
Alkaline phosphatase (ALP)	_____	(*U/L*)	
Total bilirubin	_____	(*µmol/L*)	
Gamma glutamyl transpeptidase (GGT)	_____	(*U/L*)	
Albumin	_____	(*g/L*)	
Total cholesterol	_____	(*mmol/L*)	
Glomerular Filtration Rate (GFR)	_____	*(mL/min/m^2)*	

Participant study ID: | | | | | | | |

Section 10: Blood ciclosporin levels

Participant allocated to Sandimmun® & Neoral®:

	No – Go to Section 11
	Yes – complete section below

Date of each test	**Result** (ng/mL)
d d m m y y y y	
d d m m y y y y	
d d m m y y y y	
d d m m y y y y	
d d m m y y y y	
d d m m y y y y	
d d m m y y y y	
d d m m y y y y	
d d m m y y y y	
d d m m y y y y	

Section 11: Date of 6m follow up appointment

Complete this section when a date has been allocated

d	d	m	m	y	y	y	y

Once completed, fax this CRF to the CONSTRUCT Trial Office on 01792 606599.

Do not wait for Section 11 to be completed before faxing. Refax this page once the 6m follow up appointment date is known.