Centre / Hospital Name

Participant study ID						

Please begin to complete this Case Report Form (CRF) once the participant has consented to the CONSTRUCT cohort study.

- The CRF should be completed using black ink and BLOCK CAPITALS.
- **Once Section 1 has been completed, it should be detached from the rest of the CRF, faxed separately from the rest of the CRF and stored in a secure location for data protection purposes.**
- **RCT eligibility criteria questions are written in bold. Those responses that make the participant ineligible for the RCT are in bold and have a [X].**
- 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.
- 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
- Please fax all pages in accordance with the instructions written on the relevant pages of this CRF to the CONSTRUCT Trial Office on 01792 606599.

Participant study ID							

Section 1a: Participant demographics

Title: ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Dr Other *(specify)*

Surname: _____

Forename(s): _____

Date of birth: | *d* | *d* | *m* | *m* | *y* | *y* | *y* | *y* | ***NOT eligible for the RCT if <18y [X]***

Gender: ☐ Male ☐ Female

NHS N°: | | | | | | | | | | |

Hospital N°: | | | | | | | | | | |

Home address: _____

_____

Postcode: | | | | | | | | |

Tel. No: | **0** | | | | | | | | | | |

Ethnic group: ☐ White ☐ Mixed
☐ Black ☐ Any other ethnic group *(specify)*
☐ Asian _____

Section 1b: Participant's GP details

GP full name: _____ GP ID code: _____

Practice name: _____ GP Practice code: _____

Practice address: _____

_____

Practice postcode: | | | | | | | | |

Once Section 1 has been completed, detach it, fax it to the CONSTRUCT Trial Office on 01792 606599 and then store it in a secure location away from the rest of the CRF.

Section 2: Details of presenting complaint(s)

What are the relevant presenting complaints for this episode?

(Tick all appropriate responses)

☐	No relevant symptoms			
☐	Diarrhoea……	*If so, record stool frequency*	☐	*(per day)*
☐	Bloody diarrhoea……	*If so, record bloody stool frequency*	☐	*(per day)*
☐	Abdominal pain			
☐	Tiredness			
☐	Malaise (feeling unwell)			
☐	Weight loss			
☐	Other(s) *(specify)*			

_____

_____

_____

Duration of current symptoms for this episode? ☐ *(days)*

Section 3: Past medical & surgical history

3a – Inflammatory Bowel Disease (IBD) history

Has the participant been previously diagnosed with IBD?

☐ No **If No, go straight to Section 3b**

☐ Yes If Yes, please indicate which IBD was diagnosed and complete the sub-questions

☐ **Ulcerative colitis (UC)** (please answer sub-question a)

a) Extent of disease

- ☐ *E1 – Ulcerative proctitis (limited to rectum)*
- ☐ *E2 – Left sided UC (distal to splenic flexure)*
- ☐ *E3 – Extensive UC (extends proximal to splenic flexure)*
- ☐ *Unknown disease extent*

☐ **Crohn's disease** (please answer sub-questions a-e)

a) Age at diagnosis

- ☐ *Below 16 years old*
- ☐ *Between 17 and 40 years old*
- ☐ *Above 40 years old*
- ☐ *Unknown age at diagnosis*

b) Location of disease

- ☐ *Ileal Crohn's*
- ☐ *Colonic Crohn's*
- ☐ *Ileocolonic Crohn's*
- ☐ *Isolated upper GI disease*
- ☐ *Disease location unknown*

c) Is there a concomitant upper GI disease? ☐ *Yes* ☐ *No* ☐ *Unknown*

d) Disease behaviour

- ☐ *Non-stricturing, non-penetrating*
- ☐ *Stricturing*
- ☐ *Penetrating*

e) Is there a concomitant perianal disease? ☐ *Yes* ☐ *No* ☐ *Unknown*

☐ **Indeterminate colitis** (please answer sub-question a)

a) Extent of disease

- ☐ *Proctitis (limited to rectum)*
- ☐ *Left sided colitis (distal to splenic flexure)*
- ☐ *Extensive colitis (extends proximal to splenic flexure)*
- ☐ *Unknown disease extent*

☐ **Microscopic colitis**

☐ **Unknown type of IBD**

Date of diagnosis (*nearest month and year*):

m	*m*	*y*	*y*	*y*	*y*

3b – Drug history

Please tick to indicate which drug(s) the participant has been prescribed and how long ago it was last taken. Then record the month and year the drug was <u>first</u> prescribed.

*NOTE: PARTICIPANT IS **INELIGIBLE** FOR RCT IF ANY BOXES MARKED WITH **[X]** ARE TICKED*

Drugs list	***When drugs last taken***				***Date first prescribed***					
	Never prescribed	**In the past (but not last 3m)**	**In last 3m (but not currently)**	**Taken for current episode**						
Oral steroid therapy e.g. prednisolone				*	*m*	*m*	*y*	*y*	*y*	*y*
Biological therapies e.g. Infliximab			*[X]*	*[X]*	*m*	*m*	*y*	*y*	*y*	*y*
Rosuvastatin (Crestor®)			*[X]*	*[X]*	*m*	*m*	*y*	*y*	*y*	*y*
Ciclosporin (Sandimmun®, Neoral®)			*[X]*	*[X]*	*m*	*m*	*y*	*y*	*y*	*y*
Tacrolimus (Prograf® / Fujimycin)			*[X]*	*[X]*	*m*	*m*	*y*	*y*	*y*	*y*
Azathioprine					*m*	*m*	*y*	*y*	*y*	*y*
Methotrexate					*m*	*m*	*y*	*y*	*y*	*y*
Mercaptopurine (6-MP / Puri-Nethol®)					*m*	*m*	*y*	*y*	*y*	*y*
Sulfazalazine					*m*	*m*	*y*	*y*	*y*	*y*
Mesalazine					*m*	*m*	*y*	*y*	*y*	*y*
Other aminosalicylate					*m*	*m*	*y*	*y*	*y*	*y*

* Duration of current steroid treatment (*days*):

(please specify) _____

3c – Drug allergies

Does the participant have a history of hypersensitivity to any of the following:

*NOTE: PARTICIPANT IS **INELIGIBLE** FOR RCT IF ANY BOXES MARKED WITH **[X]** ARE TICKED*

	Yes	No
Infliximab (Remicade®)	[X]	
Ciclosporin (Sandimmun® / Neoral® / Deximune®)	[X]	
Polyethoxylated oils	[X]	

3d – Co-morbidities

Please indicate which statement is correct by ticking the relevant box.

*NOTE: PARTICIPANT IS **INELIGIBLE** FOR RCT IF ANY BOXES MARKED WITH **[X]** ARE TICKED*

Ischaemic heart disease (IHD)		No history
		IHD but no recent MI
	[X]	**Acute MI in last month**
Heart failure		No history
	[X]	**Moderate / severe heart failure**
Cerebrovascular disease (CVD) & stroke		No history
		CVD but no acute stroke
	[X]	**Acute stroke within last month**
Respiratory disease		No history
		Chronic respiratory disease
	[X]	**Respiratory failure**
Renal disease		No history
		Chronic renal disease
	[X]	**Renal failure**
Hepatic (liver) disease		No history
		Chronic liver disease
	[X]	**Hepatic failure**
Immunodeficiency		No current diagnosis of immunodeficiency
	[X]	**Current diagnosis of immunodeficiency**
Active tuberculosis		No active / suspected active tuberculosis
	[X]	**Active / suspected active tuberculosis**
Severe infection		No severe infection

	[X]	**Severe infection present**
Malignancy		No current malignancy (excl. BCC)
	[X]	**Current malignancy diagnosed (not including BCC)**
Severe cognitive impairment		No
	[X]	**Severe cognitive impairment diagnosed**
Diabetes mellitus		No diagnosis of diabetes mellitus
		Type 1 diabetes mellitus
		Type 2 diabetes mellitus
		Other diabetes type e.g. LADA
		Diabetes type unknown
		Unknown whether participant has diabetes mellitus
Hypertension		No hypertension
		Participant has hypertension
		Unknown whether participant has hypertension
Hypercholesterolaemia requiring treatment		No hypercholesterolaemia requiring treatment
		Participant has hypercholesterolaemia requiring treatment
		Unknown whether participant has hypercholesterolaemia

3e – Previous surgical procedures

Please tick to indicate whether the participant has had any of the following **surgical** procedures? If they have, please record the year of surgery.

Procedures	**Unknown**	**No**	**Yes**	**If Yes, year of surgery**			
Colonic surgery				y	y	y	y
Small bowel surgery				y	y	y	y
Gastric surgery				y	y	y	y
Appendicectomy				y	y	y	y
Cholecystectomy				y	y	y	y
Open urological surgery				y	y	y	y
Open gynaecological surgery *				y	y	y	y

**Tick "No" if participant is male*

Section 4: Family & social history

4a – Family history

Does the participant have a **first degree relative** previously diagnosed with an IBD?

☐	No	***(If No, go to Section 4b)***
☐	Yes	If Yes, please complete below

Please indicate which diagnosis the parent(s) had by **ticking** in the relevant column.

Relationship	Ulcerative Colitis	Crohn's disease	Indeterminate colitis	Microscopic colitis	Unknown
Mother					
Father					

Please enter the **number** of siblings and children with a diagnosis of each IBD in the relevant column

Relationship	Ulcerative Colitis	Crohn's disease	Indeterminate colitis	Microscopic colitis	Unknown
Sibling(s)					
Child(ren)					

4b – Social history

For each question, please indicate which **ONE** statement is correct:

4b.i Participant's smoking status:

- ☐ Current smoker
- ☐ Ex-smoker
- ☐ Non-smoker (history unknown)
- ☐ Never smoked
- ☐ Unknown

4b.ii Pregnancy / lactation status:

Date of pregnancy test:	d	d	m	m	y	y	y	y

	Not applicable *(participant is female and menstruating / participant is female and post-menopausal / participant is male)*
	Participant not currently pregnant or lactating *(**MUST** be confirmed by negative pregnancy test if of child bearing age and to be considered for RCT)*
[X]	**Participant is currently pregnant** *(**MUST** be confirmed by pregnancy test wherever appropriate)*
[X]	**Participant is currently lactating and breastfeeding**

4b.iii Participant's participation in other clinical trials:

	Participant not in any other clinical trials
[X]	**Participant in another clinical trial(s)**

(If so, please specify which one(s))

_____

_____

_____

Section 5: Baseline clinical data

Please record test results that correspond closest to the **date of admission** for this episode.

Place a **cross** in the final column if the test was not done (routinely / on this occasion).

5a – Clinical measurements on admission

Measurement	Result		Test NOT done X
Weight	_____	*(Kg)*	
Height	_____	*(m)*	
Pulse	_____	*(bpm)*	
Temperature	_____	*(ºC)*	
Systolic blood pressure	_____	*(mm Hg)*	
Diastolic blood pressure	_____	*(mm Hg)*	

5b – blood results on admission

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*)	
Truelove & Witts score *(see overleaf)*	_____	**(range 0-4)**	
Glomerular Filtration Rate (GFR)	_____	*(mL/min/m^2)*	

Calculating the Truelove & Witts score - *1st stage T&W score to be calculated by determining if the patient had bloody stool frequency of 6 or more daily and any one of the following additional criteria:*

- *pulse >90 bpm;*
- *haemoglobin <10.5 g/dL;*

- *temperature >37.8^{o}C;*
- *ESR >30 mm/hr **or** CRP > 30 mg/L.*

- *Count the number of additional criteria met by the patient (up to 4) and insert this number as their T&W score.*
- *If the patient **only** has a bloody stool frequency of more than 6 per day, **enter "0".***
- *If the patient does **not** have a bloody stool frequency of more than 6 per day, **enter "0".***

5c – Endoscopy performed

Was an endoscopy performed?

	Yes
	No If No, clinical judgement of disease severity:

	Severe colitis
[X]	**Not severe colitis**

Date of endoscopy:

d	d	m	m	y	y	y	y

Endoscopic findings:

[X]	**NORMAL or inactive disease (score = 0)**
[X]	**MILD: erythema, decreased vascularity, mild friability (score = 1)**
	MODERATE: marked erythema, absent vascularity, friability, erosions (score = 2)
	SEVERE: Spontaneous bleeding, ulceration (score = 3)

5d – Stool culture results

Please indicate which of the following statements is correct:

☐ Stool culture normal (negative for infection)

☐ Growth on stool *(see notes below)*

Date of stool culture results: d d m m y y y y

Growth identified as:

- [X] **Campylobacter on stool culture**
- [X] **Salmonella on stool culture**
- [X] **Shigella on stool culture**
- ☐ C difficile
  - [X] **C difficile on stool culture**
  - ☐ C difficile on toxin ELISA *(see note #3 below)*
    - Number of positive toxin ELISA tests ☐
- [X] **Cytomegalovirus (CMV) on stool culture**
- [X] **Amoebiasis on stool culture**
- [X] **Unclassified / other infection (please specify)**

☐ Equivocal stool test result (please give details)

_____

_____

NOTES:

1) If the participant is proven to have infective colitis with NO evidence of any other IBD, they must be excluded from the cohort study by completing the **Cohort Exclusion Form**.

2) If the participant has infective colitis alongside another IBD, they may remain in the cohort.

3) A positive *C difficile* result on ELISA can be overridden by a clinical decision if the test is considered unreliable (see Section 5f). *C difficile* on stool culture excludes the patient from the RCT.

5e – Histology results

Please indicate which of the three following statements is correct:

	Histology not done – participant known to have ulcerative colitis (go to Section 5f)
[X]	**Histology reported as normal**
	Abnormalities reported on histology

Date of histology results: | d | d | m | m | y | y | y | y |

Abnormality reported as:

	Ulcerative colitis
[X]	**Crohn's disease**
	Indeterminate colitis which is…

	Clinically ulcerative colitis
[X]	**Clinically Crohn's disease**

[X]	**Cytomegalovirus (CMV) colitis**
[X]	**Microscopic colitis**
[X]	**Other histology results (please specify)**

5f – Clinical conclusion after all test results received

Conclusion:

	UC only – no other abnormal test results
	UC + results that do not exclude from RCT (e.g. C diff on ELISA)
[X]	**UC + <u>infection</u> that excludes from RCT**
[X]	**UC + <u>other cause of exclusion</u> from RCT (e.g. age <18y, pregnancy, etc)**
[X]	**Other IBD (not UC)**
[X]	**Infective colitis only**
[X]	**Other non-IBD diagnosis (specify)**

Please fax all pages completed so far to 01792 606599 as soon as possible.

Section 6: Progress (after 2 days IV steroid treatment)

NOTE: When entering data onto GeneCIS, Section 6 of the Cohort CRF: *Progress (after 2 days of IV steroids)* can be found on the separate questionnaire: '04 - Cohort Progress'

GeneCIS

After 2 days treatment with intravenous (IV) hydrocortisone, a decision should be made regarding the participant's response.

6a – Steroid treatment

6a.i Has IV hydrocortisone treatment been initiated at any point following admission?

[X] **No** ***Go to Section 6b***

[ ] Yes

Date IV steroid therapy initiated: *d d m m y y y y*

Time IV steroid therapy initiated: *h h m m* *(using 24h clock)*

Date of transfer from IV to oral steroids: *d d m m y y y y*

Date of decision regarding response to **IV** steroids: *d d m m y y y y*

6a.ii Participant's response to **IV** hydrocortisone treatment:

[X] **Good response within approx 2-5 days**

Truelove & Witts score on day 5 / at discharge (whichever is sooner): [ ]

[ ] Inadequate response within approx 2-5 days

Criteria for non-response decision:

[ ] Stool frequency >8 per day

[ ] Stool frequency of 3-8 per day with CRP > 45mg/L

[ ] Clinical judgement *(state basis for opinion)*

_____

_____

6b – Surgery

Is clinical judgement that the participant requires a colectomy without further medical treatment?

	No - COHORT CRF COMPLETED
[X]	**Yes**

Which type of surgery was performed:

	Panproctocolectomy
	Subtotal colectomy
	Ileoanal pouch with stoma
	Ileoanal pouch without stoma
	Formation of ileostomy
	Other surgical procedure (please state)

_____

Date of surgery:

d	d	m	m	y	y	y	y

You have now reached the end of the Cohort CRF.

Please fax all pages to the CONSTRUCT Trial Office on 01792 606599 as soon as possible.

If some information is outstanding, please record it as soon as possible and refax that page.

NOTE: If participant is still potentially eligible for the RCT at this point (i.e. no exclusion criteria [X] have been recorded on this Cohort CRF), please complete an **RCT Screening Form** using the responses to the eligibility questions on this CRF.