Site ☐☐☐☐☐☐☐☐☐☐☐☐☐☐ Date of form ☐☐ ☐☐☐ ☐☐☐☐

Patient Number ☐☐☐☐☐ Initials ☐☐☐ Date of birth ☐☐ ☐☐☐ ☐☐☐☐

PATIENT CASE REPORT FORM: BASELINE

Patient Consent

Patient is eligible according to the eligibility and exclusion criteria as confirmed on the screening CRF	Yes ☐ No ☐
Date of Patient Consent ……..DD/MMM/YYYY	
Patient consented to providing blood samples, which will be tested for inflammatory markers	Yes ☐ No ☐
Patient consented to providing stool samples, which will be tested for inflammatory markers	Yes ☐ No ☐
Patient consented to undergo Ultrasound scan twice by different radiologists	Yes ☐ No ☐
Patient consented to undergo hydrosonography	Yes ☐ No ☐
Patient consented to complete study questionnaires	Yes ☐ No ☐

Answers should be based on screening results, as applicable.
Please indicate if the patient has been newly diagnosed with Crohn's Disease or suspected of Luminal Relapse of Crohn's Disease, by answering the following questions:

SECTION A

Has the patient been newly diagnosed (within 3 months of screening date) with Crohn's Disease OR is highly suspected of Crohn's Disease, but pending diagnosis? *If YES, please complete the rest of Section A If your answer is NO, please complete Section B.*	Yes ☐ No ☐
Duration of symptoms, *please state*: ……(years/months)*)*	
Date of diagnosis, if pending, please state*:……..(DDMMYYYY)*	
Referral source, please circle: GP Internal External Hospital Other, *please provide detail*……..	

SECTION B *(only complete if answer to Section A is 'NO')*

Is the patient suspected of Luminal Relapse of Crohn's Disease according to Protocol Definitions? *If YES, please complete the Case Report Form for Suspected Luminal Relapse* *If your answer is NO, the patient is not eligible for this study.*	Yes ☐ No ☐
How long has the patient had Crohn's Disease? *Please state, years/months*	
Current Montreal classification	

CLINICAL DETAIL

Please provide responses to the following:	
Is the patient male or female?	Male ☐ Female ☐
Does the patient have a family history of Inflammatory Bowel Disease?	Yes ☐ No ☐ Not known ☐
Is the patient a current smoker?	Yes ☐ No ☐
Is the patient an ex-smoker?	Yes ☐ No ☐ N/A ☐
Patient height (cm) (if known)	……..cm Not known ☐
Patient weight (kg) (if known)	……kg Not known ☐

Current Crohn's Disease medication (if any)	
Drug	**Dose (if known)**

CLINICAL DETAIL

PREVIOUS BOWEL SURGERY	
Has the patient undergone previous bowel surgery? *If yes, please provide detail of surgery below*	Yes ☐ No ☐
Type of surgery (e.g. ileo-caecal resection, colectomy)	**Date (DD/MMM/YYYY *if known*)**

CLINICAL DETAIL

CROHN'S DISEASE SYMPTOMS	
Symptom	**Tick all that apply**
Diarrhoea-no blood	☐
Diarrhoea- bloody	☐
Weight loss	☐
Abdominal pain	☐
Peri-anal sepsis	☐
Obstructive symptoms	☐
Cutaneous fistulation	☐
Fever	☐
Nocturnal symptoms	☐
Uveitis	☐
Erythema nodosum	☐
Arthropathy	☐
Mouth ulcers	☐
Other (state)	☐
Other (state)	☐

Completed by:

Print name: ***Signature:*** ***Date:***

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PATIENT CASE REPORT FORM: HARVEY BRADSHAW

Thank you for agreeing to participate in this research study. Before you fill in the diary below it is important that you have read the Patient Information Sheet and the Informed Consent Form.

Symptom questionnaire

Instructions

Column A: please fill in the date

Column B: please fill in the number of liquid or very soft stools (motions) you have passed that day. For example if you have gone 5 times and two were 'normal' formed motions you would write down 3

Column C: please circle the number that most closely matches the worst pain you have felt all day (0 = none; 1 = mild; 2 = moderate; 3 = severe)

Column D: please circle the number that most closely matches how well (or unwell) you have felt during the day (0 = generally well; 1 = a bit under par; 2 = poor; 3 = very poor; 4 = terrible)

Column E: please circle 'Yes' if you have taken any medications to try and slow down your bowels (e.g. 'Imodium' (loperamide), Lomotil, codeine phosphate or any pain killers containing codeine such as cocodamol, codydramole, dichydrocodeine, DF118). If you take any pain killers for pain this does not count and you would circle 'No'. If you did not take anything to slow down the bowels then also circle 'No'

Column F: this only needs to be filled in if you have felt you have had a temperature (fever) and used a thermometer to find out

If you have any questions about how to fill in the diary, please contact your clinical care team.

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	A	B	C	D	E	F
Day	**Date**	**Number of liquid or very soft stools**	**Abdominal pain rating (circle)** **0 = none** **1 = mild** **2 = moderate** **3 = severe**	**General wellbeing (circle)** **0 = generally well** **1 = a bit under par** **2 = poor** **3 = very poor** **4 = terrible**	**Were anti-diarrhoeals taken? (circle)** e.g. loperamide, codeine phosphate or lomotil	**Temperature**
MRI			0 1 2 3	0 1 2 3 4	Yes / No	

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TO BE COMPLETED BY DOCTOR or trained nurse

Date of assessment	
Height (cm)	
Weight (kg)	
Arthritis present? *(circle one)*	**No / Yes**
Iritis or uveitis present? *(circle one)*	**No / Yes**
Erythema nodusum, pyoderma gangrenosum or aphthous stomatitis present? *(circle one)*	**No / Yes**
Anal fistula, fissure or abscess present? *(circle one)*	**No / Yes**
Other fistula present? *(circle one)*	**No / Yes**
Abdominal mass present? *(circle one)*	**No / Questionable / Yes / Yes and tender**
HCT	

NAME of assessor capitals)	
SIGNATURE	

For office use only

Received by (*print name)* Date

Entered by (*print name)* Date

PATIENT CASE REPORT FORM: CONSENSUS REFERENCE

Name and expertise of consensus panel members

Name	Expertise	State predominant imaging experience (MRI , USS or both equally)	Years of experience in Crohns disease

Date of consensus panel DD/MMM/YYYY _____

Time at start of panel discussion_____

Recruitment site_____

Patient subgroup (please tick):

New diagnosis ☐ Relapse ☐

Patient Number ☐☐☐☐☐ Initials ☐☐☐

Data considered in consensus

Test	Tick if available	Date(s) performed DD/MMM?YYYY	Consensus panel review Small bowel disease present (y-clear cut/ e-equivocal/n/na). If yes or equivocal state segments. If equivocal state (e)	Consensus panel review If present or equivocal, small bowel disease active (y, n, na)	Consensus panel review Colonic disease (y-clear cut/ e-equivocal/n/na). If yes or equivocal state segments. If equivocal state (e)	Consensus panel review If present or equivocal, colonic active (y, n, na)	Comments (if required)
example	√	11/Nov/2014	Y-TI, Jej (e)	Y	Y-R,S,C (e)	N	Chronic inactive colitis
example 2	√	14/Dec/2014	Y-Il	Y	No	N/A	
MR enterography							
Small bowel USS							
Colonoscopy			*Complete detailed colonoscopy table below*				
Gastroscopy					*Not applicable*		
Sigmoidoscopy			*Not applicable*				
Capsule endoscopy							
CT enterography							
CT abdo pelvis							
MR enteroclysis							
MRI abdomen							

and/or pelvis							
Barium FT							
Barium enteroclysis							
Hydrosonography							
White cell scan							
CRP			*Not applicable*				
HBI			*Not applicable*				
Calprotectin			*Not applicable*				
Surgical resection							
Other							
Other							
Other							

D=duodenum, Jej=jejunum, Il=ileum, TI=terminal ileum, C=caecum, A=ascending colon, T=transverse colon, D=- descending colon, S=sigmoid colon, R= rectum

Patient Number ☐☐☐☐☐ Initials ☐☐☐

Consensus overall patient status

Please State	Yes	No	Please State	Yes	No	
Any small bowel disease?			**Any colonic disease?**			
If disease is present state activity and state evidence. Tick all that apply						

	Disease NOT active	Disease active-tick evidence			
		Ulceration is seen at endoscopy	Measured CRP >8	Measured calprotectin >250	Histopathological evidence of acute inflammation based on biopsy or surgery within 2 months of trial imaging
Any active small bowel disease?					
Any active colonic disease?					

Patient Number ☐☐☐☐☐ Initials ☐☐☐

Consensus segmental disease status

Patients has a colonoscopy reference: YES ☐ NO ☐

If yes-complete table below

Colonoscopic segmental disease status	Visualised		Disease present		Photograph available		Histology available		Disease active (Presence of ulceration and /or histological acute inflammation)		Comments
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
TI											
Caecum											
Ascending											
Transverse											
Descending											
Sigmoid											
Rectum											

Patient Number ☐☐☐☐☐ Initials ☐☐☐

Overall segmental consensus reference

Complete "overall" row for each segment if just one site of disease in that segment. If more than one site (i.e. separated by >3cm normal small bowel) in a segment complete details for each site

Bowel segment	Disease present (Y/N)	Disease active (Y/N)	*MRE mislabelled location but deemed to have detected (Y/NA) -if yes state segment e.g. ileum*	*USS mislabelled location but deemed to have detected (Y /NA) -if yes state segment e.g. ileum*	MRI perceptual error? (Y, N)	USS perceptual error? (Y,N)	Length of abnormal bowel (cm)	Stensois causing functional obstruction (Y/N)	Disease early (1) or advanced (2)	If Surgical resection available, does the segmental disease show fibrosis? (Y/N/NA)	If Surgical resection or endoscopy available, is the segmental disease active? (Y/N/NA)	comments
				Example								
Overall	Y	Y	Y-il	NA	N	Y	15	Y	2	Y	Y	
Site 1	Y	Y	Y-il	NA	N	Y	10	Y	2	Y	Y	
Site 2	Y	N	NA	NA	N	N	5	N	1	Y	Y	
					Terminal ileum							
Overall												
Site 1												
Site 2												
					Ileum							
Overall												
Site 1												
Site 2												
Site 3												
Site 4												
					Jejunum							
Overall												
Site 1												
Site 2												
Site 3												

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Site 4												
					Duodenum							
Overall												
Site 1												
Site 2												
					Caecum							
Overall												
Site 1												
Site 2												
					Ascending colon							
Overall												
Site 1												
Site 2												
Site 3												
					Transverse colon							
Overall												
Site 1												
Site 2												
Site 3												
					Descending colon							
Overall												
Site 1												
Site 2												
Site 3												
					Sigmoid colon							
Site 1												
Site 2												
Site 3												
					Rectum							
Overall												
Site 1												

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Site 2												

*Please record if the consensus panel agrees MRE or USS has correctly identified the disease but have located in an alternative segment to the panel eg If the panel states that is a single segment of ileal disease, but USS reports a single segment of jejunal disease which the panel agrees is the same segment- state “Y-jej” in the appropriate USS column of the ileal segment. If MRI or US have either correctly identified the segment or missed the disease, state “NA”

Patient Number ☐☐☐☐☐ Initials ☐☐☐

Complications	Present							
	Yes	No	If yes state size			If yes state site		
Abscess								
Fistula			If yes state type					
Please state fistula type	Ileo-ileal	Ileo-colic	Entero-cutaneous	Ileo-vesical	Colon-vesical	Jejuno-jejunal	Jejuno-colic	Other (state)

Other small bowel diagnosis (e.g. adhesions, meckels, radiation enteritis etc)	Present	
	Yes	No
If yes, state diagnosis		

Other extra-enetic abnormality (e.g. aortic aneurysm gallstones, solid organ abnormality, phelgmon,)	Present	
	Yes	No
If yes, state diagnosis		

Patient Number ☐☐☐☐☐ Initials ☐☐☐

How was the consensus reached for primary outcome i.e. small bowel presence and location disease?

	Please tick	Comments
Unanimous		
Majority		
Request additional panel review (please fill as much of this CRF as possible and indicate section for requested for additional review)		
Other (state)		

Time at end of panel discussion _____

Comments

Completed by:

Print name: *Signature:* *Date:*

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Patient Number ☐☐☐☐☐ Initials ☐☐☐ Date of birth ☐☐ ☐☐☐ ☐☐☐☐

CASE REPORT FORM: DIAGNOSTIC AND THERAPUTIC IMPACT

Date of assessment ☐☐-☐☐☐-☐☐☐☐

dd mmm yyyy

Name of gastroenterologist_____

Name of Radiologist_____

Data available for this assessment (please circle one only)	Clinical and endoscopic information only	Clinical and endoscopic information PLUS conventional imaging (e.g. barium, CT)
Clinical and endoscopic information PLUS MRI	Clinical and endoscopic information PLUS US	Clinical and endoscopic information PLUS ALL imaging (i.e. final assessment)
Small bowel and colonic disease (please tick yes or no, and estimate diagnostic confidence).		
Do you think the patient has small bowel Crohn's disease?	☐ **yes** ☐ **no**	%_____
Do you think the patient has colonic Crohn's disease?	☐ **yes** ☐ **no**	%_____
IF YES COMPLETE SECTION B. IF NO, CARRY ON FROM SECTION C		

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SECTION B		
Please indicate your opinion for the presence of <u>each</u> diagnosis (where applicable) and circle a number to estimate your diagnostic certainty , as follows:		
1=No **2=Unlikely**	**3=Possible** **4=Probable**	**5=Almost Certainly** **6=Yes** **NA=not applicable**
Small bowel Extent A) Is the small bowel disease extensive (>30cm)?	1 2 3 4 5 6	
B) Does the disease affect the terminal ileum only?	1 2 3 4 5 6	
C) Is there upper GI or jejunal disease (as opposed to ileal disease only)	1 2 3 4 5 6	
<u>Stricture</u> A) Is there a small bowel stricture present?	1 2 3 4 5 6	
If judged at least "possible" B) What is the nature of the stricture	Definitely fibrostenotic/ probably fibrostenotic/ uncertain/ probably inflammatory/ definitely inflammatory	
<u>Disease activity</u> A) Is the small bowel disease Active (as opposed to non active)	1 2 3 4 5 6	
Colonic disease A) Is there Colonic disease present	1 2 3 4 5 6	
If judged at least "possible" B) Is the colonic disease extensive (>2 colonic segments)	1 2 3 4 5 6	

Please indicate your opinion for the presence of <u>each</u> diagnosis (where applicable) and circle a number to estimate your diagnostic certainty , as follows:

1=No **2=Unlikely**	**3=Possible** **4=Probable**	**5=Almost Certainly** **6=Yes** **NA=not applicable**

<u>Extra-luminal complications</u> Is there an						
Entero-enteric fistula	1	2	3	4	5	6
Entero-colic fistula	1	2	3	4	5	6
Enterovaginal fistula	1	2	3	4	5	6
Entero-vesical fistula	1	2	3	4	5	6
Inflammatory mass	1	2	3	4	5	6
Abscess	1	2	3	4	5	6
Will the patient require surgery for Crohns disease within 3 months	1	2	3	4	5	6

B2) Proposed L and B Montreal classification (based on above). Please see definitions.

_____

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SECTION C

What other tests would you now request (if not already done)? Please tick any that apply.	
None	☐
MRI enterography	☐
Barium Follow through	☐
CT enterography	☐
CT abdomen and pelvis	☐
Abdo USS	☐
Flexi sig	☐
Colonoscop	☐
Blood tests	☐
Capsule endoscopy	☐
Other (please state)	☐

SECTION D Patient Management

How would you most likely manage the patient? Please tick one of the following, providing details, if necessary.

		FURTHER DETAILS
Patient is on no medication for active Crohn's and none will be added	☐	
Patient is not on medication for active Crohn's but will be started on some	☐	
Maintain current medication for active Crohn's	☐	
Reduce dose of current medication for active Crohn's	☐	
Increase dose of current medication for active Crohn's	☐	
Stop current medication for active Crohn's	☐	
Change current medication for active Crohn's to similar drug class (eg conventional or biological)	☐	
Change current medication for active Crohn's to different drug class (eg from conventional to biological)	☐	
Refer for surgical therapy	☐	
Other (please state)	☐	

Completed by:

Print name: *Signature:*

Date:

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Month	0 - 3

Patient Resource Use Diary

Each diary covers a three month period

This diary is to help you keep a record of contacts you make with the NHS about your Crohn's disease. A contact is any visit you attend at your hospital/GP or other eg. Physio related to your Crohn's disease. This will allow us to calculate the cost to the NHS of your care so we can help with the planning of NHS services in the future.

Please record as accurately as possible the number of contacts you make each week about your Crohn's disease, indicating who you contacted and how. We would like you to record contacts you have had with the hospital and with your GP and community care services. You will see there is one table for hospital visits and one for contacts with your GP and community services, and we ask you to complete both of these, please. There is a third blank table for you to record any visits which do not fit into the other two tables. An example may be a session of acupuncture or physiotherapy. Please also record the medications you take because of your Crohn's disease on the last table in the form.

You might find that the easiest way to record the contacts you have made is to put a tick in the appropriate column each time you make a contact, or to write the number of contacts down each week. It should not take you more than a few minutes each week and you may find it useful to keep a copy for your own records.

Here is an example of a completed week for hospital contacts:

	You are treated overnight in a hospital *(Please record the number of stays and the number of nights for each stay)*		**You had an appointment to receive treatment (e.g. infliximab infusion)** *(Please record the number of appointments you attended)*	**You had an appointment for endoscopy** *(Please record the number of appointments you attended)*	**You had an appointment to have a scan such as CT, ultrasound or MRI scan** *(Please record the number of scan appointments you attended)*	**You were admitted to a day ward in hospital without staying overnight (not routine drug administration such as infliximab)** *(Please record the number of days)*	**You had an appointment with a doctor or nurse in the hospital or attended a clinical appointment such as outpatients (not routine drug administration such as infliximab)** *(Please record the number of appointments you attended)*	**You were treated at the Accident and Emergency Department** *(Please record the number of times)*
	No of Stays	No of Nights						
Week 1	1 2	1 3	0	0	1	0	1	1

This example would tell us that during week 1 this person was treated overnight in a hospital for 4 nights over 2 stays, that they had one outpatient appointment for something other than routine medication, they attended the hospital for one scan, and that they had one accident and emergency visit.
Please only record those contacts related to your Crohn's disease.

Thank you for taking the time to complete this form.

Please return in the stamped address envelope you were provided with when you have completed the diary for the three month period covered. If you no longer have your stamped address envelope please contact the hospital who recruited you to the trial.

Record of hospital contacts

Please record the contacts you have had with the hospital services.

	You are treated overnight in a hospital *(Please record the number of stays and the number of nights for each stay)*		**You had an appointment to receive treatment (e.g. infliximab infusion)** *(Please record the number of appointments you attended)*	**You had an appointment for endoscopy** *(Please record the number of appointments you attended)*	**You had an appointment to have a scan such as CT, ultrasound or MRI scan** *(Please record the number of scan appointments you attended)*	**You were admitted to a day ward in hospital without staying overnight (not routine drug administration such as infliximab)** *(Please record the number of days)*	**You had an appointment with a doctor or nurse in the hospital or attended a clinical appointment such as outpatients (not routine drug administration such as infliximab)** *(Please record the number of appointments you attended)*	**You were treated at the Accident and Emergency Department** *(Please record the number of times)*
	No of Stays	No of Nights						
Week 1								
Week 2								
Week 3								
Week 4								
Week 5								
Week 6								
Week 7								
Week 8								
Week 9								
Week 10								
Week 11								
Week 12								

Please only record those contacts related to your Crohn's disease

Record of primary care and community care contacts

Please record the contacts you have had with GP and community care services.

	You visit your GP at the GP practice or health centre *(Please record the number of visits)*	**Your GP visits you at home** *(Please record the number of visits)*	**You speak with your GP over the telephone** *(Please record the number of contacts)*	**You visit an NHS nurse at the GP practice or health centre** *(Please record the number of visits)*	**An NHS nurse visits you at home** *(Please record the number of visits)*	**You speak with an NHS nurse over the telephone** *(Please record the number of contacts)*
Week 1						
Week 2						
Week 3						
Week 4						
Week 5						
Week 6						
Week 7						
Week 8						
Week 9						
Week 10						
Week 11						
Week 12						

Please only record those contacts related to your Crohn's disease.

Record of other contacts

Please record in this table any other NHS contacts you have had to do with your Crohn's disease which are not recorded in the tables above. Please record the type of contact or health care professional that you contacted, where the contact took place (e.g., at home, at the hospital, at the GP practice or health centre) and the number of contacts over the whole 12 week period.

Type of contact	**Where the contact took place**	**Number of contacts**
Physiotherapy	Physiotherapy Centre	2

Please only record those contacts related to your Crohn's Disease.

Record of medications

Please record in the table below the medications you take during the 12 week period. Please record the name of the medication, the dosage you take each time, the number of doses you take each day, and the number of days you take the medication. Please also record whether the medication was prescribed by a doctor or nurse, or bought over the counter.

We realise you may not know the details of any medicines you receive in hospital, so just list "medicines in the hospital" if you are not sure.
Please only record the medications you have taken that are related to your Crohn's disease
If you are admitted to hospital, please try and continue to fill in this table if possible.

Name of medication	**Dosage**	**Number of doses per day**	**Number of days**	**Prescribed by a doctor or nurse, or bought over the counter**
EXAMPLE: Panadol	*250mg*	*Twice a day*	*3 days*	*Over the counter*

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PATIENT CASE REPORT FORM: MRI INTERPRETATION

Radiologist Initials_____

MRI platform_____

Central review (due to unblinding at recruitment site) Y/N

Are you blinded to other clinical tests and investigations and patient clinical history (other than previous surgical history and new diagnosis or relapse cohort) Y/N

If N state what information/ test data you are aware of (e.g. barium FT)_____

Segment	**Quality of segmental visualisation to make correct diagnosis** **1-good/ 2-moderate/ 3-poor/ 4-N/A or excised**				**If poor visualisation, tick why** **1- poor distension/ *2- oral contrast not reached segment/ 3-Other (state)***		
	1	2	3	4	1	2	3
duodenum							
Jejunum*							
ileum							
Terminal ileum**							
Caecum							
Ascending							
Transverse							
Descending							
Sigmoid							
Rectum							

* small bowel from DJ flexure mainly to the left of a diagonal running from the RUQ to LLQ showing typical feathery fold pattern, ** last 10cm of ileum upstream of IV valve/anastomosis

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PATIENT CASE REPORT FORM: MRI INTERPRETATION

Overall disease assessment (to be completed for all patients)						
	Normal		**Equivocal**		**Abnormal**	
Confidence of presence	1 (disease definitely not present)	2 (disease probably not present)	3 (disease possibly not present)	4 (disease possibly present)	5 (disease probably present)	6 (disease definitely present)
Any small bowel disease PRESENT?- tick confidence box						
Confidence of activity	1 (disease definitely not active)	2 (disease probably not active)	3 (disease possibly not active)	4 (disease possibly active)	5 (disease probably active)	6 (disease definitely active)
If present (confidence score ≥3) is it ACTIVE? tick confidence box						
Confidence of presence	1 (disease definitely not present)	2 (disease probably not present)	3 (disease possibly not present)	4 (disease possibly present)	5 (disease probably present)	6 (disease definitely present)
Any colonic disease PRESENT? tick confidence box						
Confidence of activity	1 (disease definitely not active)	2 (disease probably not active)	3 (disease possibly not active)	4 (disease possibly active)	5 (disease probably active)	6 (disease definitely active)
If present (confidence score ≥3) is it ACTIVE? tick confidence box						

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Lymphadenopathy (0-3)	☐ **0**	☐ **1**	☐ **2**	☐ **3**
Abnormal free fluid (Y/N)	☐ **Yes**		☐ **No**	
Abscess present	☐ **Yes**		☐ **No**	
If yes please state size & location				
Fistula present (circle all that apply)	☐ **Yes**		☐ **No**	
If yes please circle location		Ileo-ileal Ileo-colic entero-cutaneous ileo-vesical colon-vesical jejuno- jejunal jejuno-colic Other (state_____)		
Other small bowel diagnosis (e.g. adhesions, meckels, radiation enteritis etc	☐ **Yes**		☐ **No**	
If yes please state				
Extra enteric findings (e.g. aortic aneurysm gallstones, solid organ abnormality, phelgmon)	☐ **Yes**		☐ **No**	
If yes please state				
Are you recommending any further tests?	☐ **Yes**		☐ **No**	
If yes please state which				

UCL Clinical Trials Unit, Gower Street, London, WC1E 6BT

Tel: 020 3108 3263 Email: metric@ucl.ac.uk

PATIENT CASE REPORT FORM: MRI INTERPRETATION

Please complete for each segment

Confidence of disease PRESENCE

	Normal		Equivocal		Abnormal	
Segment	1 (disease definitely not present)	2 (disease probably not present)	3 (disease possibly not present)	4 (disease possibly present)	5 (disease probably present)	6 (disease definitely present)
Duodenum (D)						
Jejunum (J)						
Ileum (I)						
Terminal ileum (TI)*						
Caecum (C)						
Ascending colon (A)						
Transverse colon (T)						
Descending colon (D)						
Sigmoid (S)						
Rectum (R)						

*throughout, if TI disease is contiguous for over 10cm count just as TI not TI and ileum

PATIENT CASE REPORT FORM: MRI INTERPRETATION

METRIC

Patient Number ☐☐☐☐☐ **Initials** ☐☐☐

Confidence of disease ACTIVITY Please complete for each segment if confidence scores 3-6 for disease presence above i.e. present or equivocal

		Normal		Equivocal		Active	
Segment	No disease (i.e. confidence scores 1 or 2 for disease presence)	1 (disease definitely not active)	2 (disease probably not active)	3 (disease possibly not active)	4 (disease possibly active)	5 (disease probably active)	6 (disease definitely active)
Duodenum (D)							
Jejunum (J)							
Ileum (I)							
Terminal ileum (TI)							
Caecum (C)							
Ascending colon (A)							
Transverse colon (T)							
Descending colon (D)							
Sigmoid (S)							
Rectum (R)							

PATIENT CASE REPORT FORM: MRI INTERPRETATION Disease Description Please complete for each disease site (defined as >3cm of normal bowel between disease sites). Use one table for each disease site. Only record segments which if you have a confidence score of 3 or more for disease presence. *Use score definitions at the start of this CRF*

DISEASE SITE 1

Location	Tick one location	Single Wall thickness (mm) thickest portion	Wall thickening	Length of abnormal bowel (cm)	Stensois causing functional obstruction	Peri-mural T2 signal	Mural T2 signal	Ulceration	Contrast enhancement	Contrast enhancement pattern	Diffusion signal	Does the segment contain established fibrosis (Y/N)	Segmental disease severity assessment	Segment shows active disease (Y/N)
Duo														
J														
I														
TI														
C														
A														
Des														
S														
R														

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PATIENT CASE REPORT FORM: MRI INTERPRETATION Disease Description Please complete for each disease site (defined as >3cm of normal bowel between disease sites). Use one table for each disease site. Only record segments which if you have a confidence score of 3 or more for disease presence. *Use score definitions at the start of this CRF*

DISEASE SITE 2

Location	Tick one location	Single Wall thickness (mm) thickest portion	Wall thickening	Length of abnormal bowel (cm)	Stensois causing functional obstruction	Peri-mural T2 signal	Mural T2 signal	Ulceration	Contrast enhancement	Contrast enhancement pattern	Diffusion signal	Does the segment contain established fibrosis (Y/N)	Segmental disease severity assessment	Segment shows active disease (Y/N)
Duo														
J														
I														
TI														
C														
A														
Des														
S														
R														

UCL Clinical Trials Unit, Gower Street, London, WC1E 6BT
Tel: 020 3108 3263 Email: metric@ucl.ac.uk

PATIENT CASE REPORT FORM: MRI INTERPRETATION Disease Description Please complete for each disease site (defined as >3cm of normal bowel between disease sites). Use one table for each disease site. Only record segments which if you have a confidence score of 3 or more for disease presence. *Use score definitions at the start of this CRF*

DISEASE SITE 3

Location	Tick one location	Single Wall thickness (mm) thickest portion	Wall thickening	Length of abnormal bowel (cm)	Stensois causing functional obstruction	Peri-mural T2 signal	Mural T2 signal	Ulceration	Contrast enhancement	Contrast enhancement pattern	Diffusion signal	Does the segment contain established fibrosis (Y/N)	Segmental disease severity assessment	Segment shows active disease (Y/N)
Duo														
J														
I														
TI														
C														
A														
Des														
S														
R														

UCL Clinical Trials Unit, Gower Street, London, WC1E 6BT
Tel: 020 3108 3263 Email: metric@ucl.ac.uk

PATIENT CASE REPORT FORM: MRI INTERPRETATION Disease Description Please complete for each disease site (defined as >3cm of normal bowel between disease sites). Use one table for each disease site. Only record segments which if you have a confidence score of 3 or more for disease presence. *Use score definitions at the start of this CRF*

DISEASE SITE 4

Location	Tick one location	Single Wall thickness (mm) thickest portion	Wall thickening	Length of abnormal bowel (cm)	Stensois causing functional obstruction	Peri-mural T2 signal	Mural T2 signal	Ulceration	Contrast enhancement	Contrast enhancement pattern	Diffusion signal	Does the segment contain established fibrosis (Y/N)	Segmental disease severity assessment	Segment shows active disease (Y/N)
Duo														
J														
I														
TI														
C														
A														
Des														
S														
R														

Please attach additional pages if required. If additional pages added, insert total number of additional pages used: _____page(s)

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Tel: 020 3108 3263 Email: metric@ucl.ac.uk

PATIENT CASE REPORT FORM: MRI INTERPRETATION: Additional Sequences		
	Diffusion weighted	**Contrast enhanced**
Not helpful	☐	☐
Diagnosis unchanged but increased confidence	☐	☐
Diagnosis changed-additional disease site detected	☐	☐
Diagnosis changed-disease site now discounted	☐	☐
Diagnosis changed –disease re-classified as active	☐	☐
Diagnosis changed –disease re-classified as inactive	☐	☐
Other-state		

Completed by:

Print name: *Signature:* *Date:*

Office Use Only:

Received by (Print name & sign): *Date:* *Entered by: (Print name & sign):* *Date:*

UCL Clinical Trials Unit, Gower Street, London, WC1E 6BT

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METRIC

Site ☐☐☐☐☐☐☐☐☐☐☐☐☐☐ **Date of form** ☐☐ ☐☐☐ ☐☐☐☐

Patient Number ☐☐☐☐☐ **Initials** ☐☐☐ **Date of birth** ☐☐ ☐☐☐ ☐☐☐☐

PATIENT CASE REPORT FORM: US INTERPRETATION

Radiologist Initials_____

USS platform_____

Are you blinded to other clinical tests and investigations and patient clinical history (other than previous surgical history and new diagnosis or relapse cohort) ☐ **Yes** ☐ **No**

If N state what information/ test data you are aware of (eg barium FT)_____

Scan type (please circle)

Main Metric trial scan Hydosonography substudy Reader agreement substudy

If main Metric scan is this a repeat USS due to unblinded first USS examination? ☐ **Yes** ☐ **No**

Hydrosonography sub study			
Performed using oral contrast given for same day MRE (circle)	☐ **Yes**	☐ **No**	
Type of oral contrast		**Volume ingested**	
Time for ingestion			

PATIENT CASE REPORT FORM: US INTERPRETATION: Scan quality

Segment	Quality of segmental visualisation to make correct diagnosis 1-good/ 2-moderate/ 3-poor/ 4-N/A or excised				If poor visualisation, tick why 1- overlying bowel gas/ *2- increased patient BM/ 3-Difficult anatomy***/ 4-patient pain/ 5-other (state)*				
	1	2	3	4	1	2	3	4	5
duodenum									
Jejunum*									
ileum									
Terminal ileum**									
Caecum									
Ascending									
Transverse									
Descending									
Sigmoid									
Rectum									

* small bowel from DJ flexure mainly to the left of a diagonal running from the RUQ to LLQ showing typical feathery fold pattern,

** last 10cm of ileum upstream of IV valve/anastomosis

***E.g. low lying caecum

Ileocaecal valve identified ☐ **Yes** ☐ **No**

PATIENT CASE REPORT FORM: US INTERPRETATION Disease Assessment

Overall disease assessment (to be completed for all patients)						
	Normal		**Equivocal**		**Abnormal**	
Confidence	1 (disease definitely not present)	2 (disease probably not present)	3 (disease possibly not present)	4 (disease possibly present)	5 (disease probably present)	6 (disease definitely present)
Any small bowel disease PRESENT?- tick confidence box						
	1 (disease definitely not active)	2 (disease probably not active)	3 (disease possibly not active)	4 (disease possibly active)	5 (disease probably active)	6 (disease definitely active)
If present (confidence score ≥3) is it ACTIVE? tick confidence box						
	1 (disease definitely not present)	2 (disease probably not present)	3 (disease possibly not present)	4 (disease possibly present)	5 (disease probably present)	6 (disease definitely present)
Any colonic disease PRESENT? tick confidence box						
	1 (disease definitely not active)	2 (disease probably not active)	3 (disease possibly not active)	4 (disease possibly active)	5 (disease probably active)	6 (disease definitely active)
If present (confidence score ≥3) is it ACTIVE? tick confidence box						

PATIENT CASE REPORT FORM: US INTERPRETATION Other findings

Lymphadenopathy (0-3)	☐ **0**	☐ **1**	☐ **2**	☐ **3**
Abnormal free fluid (Y/N)	☐ **Yes**		☐ **No**	
Abscess present	☐ **Yes**		☐ **No**	
If yes please state size & location				
Fistula present (circle all that apply)	☐ **Yes**		☐ **No**	
If yes please circle location		Ileo-ileallleo-colic entero-cutaneous ileo-vesical colon-vesicaljejuno- jejunaljejuno-colic Other (state_____)		
Other small bowel diagnosis (e.g. adhesions, meckels, radiation enteritis etc	☐ **Yes**		☐ **No**	
If yes please state				
Extra enteric findings (e.g. aortic aneurysm gallstones, solid organ abnormality, phelgmon)	☐ **Yes**		☐ **No**	
If yes please state				
Are you recommending any further tests?	☐ **Yes**		☐ **No**	
If yes please state which				

PATIENT CASE REPORT FORM: US INTERPRETATION Disease Presence

Please complete for each segment

Confidence of disease PRESENCE

	Normal		Equivocal		Abnormal	
Segment	1 (disease definitely not present)	2 (disease probably not present)	3 (disease possibly not present)	4 (disease possibly present)	5 (disease probably present)	6 (disease definitely present)
Duodenum (D)						
Jejunum (J)						
Ileum (I)						
Terminal ileum (TI)*						
Caecum (C)						
Ascending colon (A)						
Transverse colon (T)						
Descending colon (D)						
Sigmoid (S)						
Rectum (R)						

*throughout, if TI disease is contiguous for over 10cm count just as TI not TI and ileum

PATIENT CASE REPORT FORM: US INTERPRETATION Disease Activity

Confidence of disease ACTIVITY Please complete for each segmentif confidence scores 3-6 for disease presence above i.e. **present or equivocal**

		Normal		Equivocal		Active	
Segment	No disease (i.e. confidence scores 1 or 2 for disease presence)	1 (disease definitely not active)	2 (disease probably not active)	3 (disease possibly not active)	4 (disease possibly active)	5 (disease probably active)	6 (disease definitely active)
Duodenum (D)							
Jejunum (J)							
Ileum (I)							
Terminal ileum (TI)							
Caecum (C)							
Ascending colon (A)							
Transverse colon (T)							
Descending colon (D)							
Sigmoid (S)							
Rectum (R)							

PATIENT CASE REPORT FORM: US INTERPRETATION Disease Description Disease Site 1

PLEASE COMPLETE FOR EACH DISEASE SITE (DEFINED AS >3CM OF NORMAL BOWEL BETWEEN DISEASE SITES). USE ONE TABLE FOR EACH DISEASE SITE. ONLY RECORD SEGMENTS WHICH IF YOU HAVE A CONFIDENCE SCORE OF 3 OR MORE FOR DISEASE PRESENCE. USE SCORE DEFINITIONS AT THE START OF THIS CRF

Complete for equivocal or abnormal sites (i.e. confidence scores 3-6). Complete additional tables as required if multiple disease sites per segment

Location	Tick one location	Single Wall thickness (mm) thickest portion	Wall thickening	Length of abnormal bowel (cm)	Stensois causing functional obstruction	Mesenteric fat echogenicity	Anti-mesenteric border	Mesenteric border	Submucosal layer	Submucosal layer echogenicity	Submucosal layer clarity	Mucosal layer	Ulceration	Doppler vascular pattern axial section	Peristaltic distension	Does the segment contain established fibrosis (Y/N)	Segmental disease severity assessment	Segment shows active disease (Y/N)
Duo																		
J																		
I																		
TI																		
C																		
A																		
Des																		
S																		
R																		

PATIENT CASE REPORT FORM: US INTERPRETATION Disease Description Disease Site 2

PLEASE COMPLETE FOR EACH DISEASE SITE (DEFINED AS >3CM OF NORMAL BOWEL BETWEEN DISEASE SITES). USE ONE TABLE FOR EACH DISEASE SITE. ONLY RECORD SEGMENTS WHICH IF YOU HAVE A CONFIDENCE SCORE OF 3 OR MORE FOR DISEASE PRESENCE. USE SCORE DEFINITIONS AT THE START OF THIS CRF

Complete for equivocal or abnormal sites (i.e. confidence scores 3-6). Complete additional tables as required if multiple disease sites per segment

Location	Tick one location	Single Wall thickness (mm) thickest portion	Wall thickening	Length of abnormal bowel (cm)	Stensois causing functional obstruction	Mesenteric fat echogenicity	Anti-mesenteric border	Mesenteric border	Submucosal layer	Submucosal layer echogenicity	Submucosal layer clarity	Mucosal layer	Ulceration	Doppler vascular pattern axial section	Peristaltic distension	Does the segment contain established fibrosis (Y/N)	Segmental disease severity assessment	Segment shows active disease (Y/N)
Duo																		
J																		
I																		
TI																		
C																		
A																		
Des																		
S																		
R																		

PATIENT CASE REPORT FORM: US INTERPRETATION Disease Description Disease Site 3

PLEASE COMPLETE FOR EACH DISEASE SITE (DEFINED AS >3CM OF NORMAL BOWEL BETWEEN DISEASE SITES). USE ONE TABLE FOR EACH DISEASE SITE. ONLY RECORD SEGMENTS WHICH IF YOU HAVE A CONFIDENCE SCORE OF 3 OR MORE FOR DISEASE PRESENCE. USE SCORE DEFINITIONS AT THE START OF THIS CRF

Complete for equivocal or abnormal sites (i.e. confidence scores 3-6). Complete additional tables as required if multiple disease sites per segment

Location	Tick one location	Single Wall thickness (mm) thickest portion	Wall thickening	Length of abnormal bowel (cm)	Stensois causing functional obstruction	Mesenteric fat echogenicity	Anti-mesenteric border	Mesenteric border	Submucosal layer	Submucosal layer echogenicity	Submucosal layer clarity	Mucosal layer	Ulceration	Doppler vascular pattern axial section	Peristaltic distension	Does the segment contain established fibrosis (Y/N)	Segmental disease severity assessment	Segment shows active disease (Y/N)
Duo																		
J																		
I																		
TI																		
C																		
A																		
Des																		
S																		
R																		

PATIENT CASE REPORT FORM: US INTERPRETATION Disease Description Disease Site 4

PLEASE COMPLETE FOR EACH DISEASE SITE (DEFINED AS >3CM OF NORMAL BOWEL BETWEEN DISEASE SITES). USE ONE TABLE FOR EACH DISEASE SITE. ONLY RECORD SEGMENTS WHICH IF YOU HAVE A CONFIDENCE SCORE OF 3 OR MORE FOR DISEASE PRESENCE. USE SCORE DEFINITIONS AT THE START OF THIS CRF

Complete for equivocal or abnormal sites (i.e. confidence scores 3-6). Complete additional tables as required if multiple disease sites per segment

Location	Tick one location	Single Wall thickness (mm) thickest portion	Wall thickening	Length of abnormal bowel (cm)	Stensois causing functional obstruction	Mesenteric fat echogenicity	Anti-mesenteric border	Mesenteric border	Submucosal layer	Submucosal layer echogenicity	Submucosal layer clarity	Mucosal layer	Ulceration	Doppler vascular pattern axial section	Peristaltic distension	Does the segment contain established fibrosis (Y/N)	Segmental disease severity assessment	Segment shows active disease (Y/N)
Duo																		
J																		
I																		
TI																		
C																		
A																		
Des																		
S																		
R																		

PATIENT CASE REPORT FORM: US INTERPRETATION Disease Description Disease Site 5

PLEASE COMPLETE FOR EACH DISEASE SITE (DEFINED AS >3CM OF NORMAL BOWEL BETWEEN DISEASE SITES). USE ONE TABLE FOR EACH DISEASE SITE. ONLY RECORD SEGMENTS WHICH IF YOU HAVE A CONFIDENCE SCORE OF 3 OR MORE FOR DISEASE PRESENCE. USE SCORE DEFINITIONS AT THE START OF THIS CRF

Complete for equivocal or abnormal sites (i.e. confidence scores 3-6). Complete additional tables as required if multiple disease sites per segment

Location	Tick one location	Single Wall thickness (mm) thickest portion	Wall thickening	Length of abnormal bowel (cm)	Stensois causing functional obstruction	Mesenteric fat echogenicity	Anti-mesenteric border	Mesenteric border	Submucosal layer	Submucosal layer echogenicity	Submucosal layer clarity	Mucosal layer	Ulceration	Doppler vascular pattern axial section	Peristaltic distension	Does the segment contain established fibrosis (Y/N)	Segmental disease severity assessment	Segment shows active disease (Y/N)
Duo																		
J																		
I																		
TI																		
C																		
A																		
Des																		
S																		
R																		

PATIENT CASE REPORT FORM: US INTERPRETATION Disease Description Disease Site 6

PLEASE COMPLETE FOR EACH DISEASE SITE (DEFINED AS >3CM OF NORMAL BOWEL BETWEEN DISEASE SITES). USE ONE TABLE FOR EACH DISEASE SITE. ONLY RECORD SEGMENTS WHICH IF YOU HAVE A CONFIDENCE SCORE OF 3 OR MORE FOR DISEASE PRESENCE. USE SCORE DEFINITIONS AT THE START OF THIS CRF

Complete for equivocal or abnormal sites (i.e. confidence scores 3-6). Complete additional tables as required if multiple disease sites per segment

Location	Tick one location	Single Wall thickness (mm) thickest portion	Wall thickening	Length of abnormal bowel (cm)	Stensois causing functional obstruction	Mesenteric fat echogenicity	Anti-mesenteric border	Mesenteric border	Submucosal layer	Submucosal layer echogenicity	Submucosal layer clarity	Mucosal layer	Ulceration	Doppler vascular pattern axial section	Peristaltic distension	Does the segment contain established fibrosis (Y/N)	Segmental disease severity assessment	Segment shows active disease (Y/N)
Duo																		
J																		
I																		
TI																		
C																		
A																		
Des																		
S																		
R																		

Completed by:

Print name: *Signature:* *Date:*

Office Use Only:

Received by (Print name & sign): *Date:* *Entered by: (Print name & sign):* *Date:*

METRIC Patient Informed Consent Form

Version 10.0, -- May, 2015

This Informed Consent Form is intended for consenting patients into the METRIC study

MREnterography or ulTRasound In Crohn's disease (METRIC)

Please initial the boxes to confirm consent:

1	I confirm that I have read and understand the Patient Information Sheet (Version 10.0, -- 15 June , 2015) for the METRIC study and have had the opportunity to ask questions which have been answered to my satisfaction.	[ ]
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 images and data collected during this study, may be looked at by authorised individuals from University College London, 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.	[ ]
4	I understand that my taking part in this study will mean that I have additional tests.	[ ]
5	I agree to my anonymised imaging and clinical data acquired during the METRIC study being used now and in future ethically approved research related to Crohn's Disease	[ ]
6	I agree to take part in the METRIC study.	[ ]

OPTIONAL TESTS, ***These are optional tests; declining to participate in them will not prevent you taking part in the METRIC study.***		
7	I consent to providing blood samples, which will be tested for inflammatory markers	[ ]
8	I consent to providing stool samples, which will be tested for inflammatory markers	[ ]
9	I consent and agree to complete questionnaires specific to this study.	[ ]
10	I consent to take part in the sub study which requires me to undergo hydrosonography and I understand that this test involves drinking up to 1L of fluid	[ ]

11	I consent for relevant results from tests and questionnaires performed as part of my usual clinical care before consenting to join the trial to be used -retrospectively by the research team if needed.	[ ]
12	I agree to my GP being informed of my participation in this study	[ ]

Patient Name	Date	Signature
Person taking Consent	Date	Signature
Witness (if applicable)	Date	Signature

METRIC

Site | | Date of form | | |

Patient Number | | Initials | | Date of birth | | |

PATIENT CASE REPORT FORM: MEDICAL TREATMENT, INVESTIGATIONS AND INTERVENTIONS: 0-3 MONTHS

MEDICATIONS

MEDICATION PATIENT RECEIVED FOR CROHN'S DISEASE ***(e.g. azathioprine, methotrexate, steroids, Infliximab, Humira etc.)***	
Drug	**Dose (if known)**

PATIENT CASE REPORT FORM: MEDICAL TREATMENT, INVESTIGATIONS AND INTERVENTIONS: 0-3 MONTHS Include all tests performed following recruitment

IMAGING AND ENDOSCOPY

IMAGING TESTS AND ENDOSCOPY PERFORMED

(Do include tests performed in diagnostic work up already documented on the "Endoscopic and imaging interventions CRF")

Test	**Number performed over time period**	**Dates Performed**
Example	*2*	*12/2/14, 18/3/14*
Colonoscopy		
Flexible sigmoidoscopy		
Capsule endoscopy		
MRI small bowel		
Ultrasound small bowel		
CT enterography		
CT enteroclysis		
CT abdomen and pelvis		
MRI enteroclysis		
Barium follow though		
Barium enteroclysis		
MRI pelvis		
Other (state)		
Other (state)		

PATIENT CASE REPORT FORM: MEDICAL TREATMENT, INVESTIGATIONS AND INTERVENTIONS: 0-3 MONTHS

STUDY 0-3MONTHSSURGICAL TREATMENT

PROCEDURE (e.g. ileal resection, colectomy, pouch formation, anal fistula lay open, EUA etc.)	DATES PERFORMED	DAY CASE (Y/N)	NUMBER OF IN PATIENT DAYS (I.E. OVERNIGHT STAY IF NOT DAY CASE)
Total days			

PATIENT CASE REPORT FORM: MEDICAL TREATMENT, INVESTIGATIONS AND INTERVENTIONS: 0-3 MONTHS

3MONTHSCROHN'S RELATED OUTPATIENT VISITS

OUTPATIENT VISITS (excluding visits or Crohn's related therapy e.g. infliximab infusions)	
Total number outpatient visits over time period	
Day case VISITS for Crohn's therapy (e.g. infliximab infusions)	
Total number day case treatment visits over time period	

Drug e.g. infliximab, humira etc)	**Total number of day case visits**	**Total number of inpatient days (i.e. with overnight stay) if applicable**

PATIENT CASE REPORT FORM: MEDICAL TREATMENT, INVESTIGATIONS AND INTERVENTIONS: 0-3 MONTHS

Day case VISITS - OTHER

Day case VISITS (Other day case visits excluding planned Crohn's treatment	
Total number outpatient visits over time period	
REASON (e.g. blood transfusion)	**Date**

PATIENT CASE REPORT FORM: MEDICAL TREATMENT, INVESTIGATIONS AND INTERVENTIONS: 0-3 MONTHS

INPATIENT stays-excluding those related to surgery recorded above

INPATIENT Stays		
REASON (E.G. FLARE OF CROHNS, INFECTION)	**DATES**	**TOTAL NUMBER OF INPATIENT DAYS (I.E. WITH OVERNIGHT STAY)**

Completed by:

Print name: *Signature:* *Date:*

Office Use Only:

Received by (Print name & sign): *Date:* *Entered by: (Print name & sign):* *Date:*