This form gathers core data on Adult IBD patients. **Please complete all * marked questions**. Shaded areas must be completed by clinicians and patient demographics can be completed by a non-clinical staff. A summary report will be available to download to save time in future consultations.

NIHR | BioResource

Attach barcode here

IBD

IBD BioResource Adult Clinical Data sheet

(Version 6.0 23/11/21)

Patient Name:

Hospital No:

NHS No:

Designation of person(s) extracting data: ☐ Doctor
☐ IBD Nurse ☐ Research Nurse ☐ Other (*please state*)
_____

*Is the patient under 16? ☐ Yes ☐ No

If 'Yes', the patient should join the Paediatric IBD BioResource

Clinical Details:

*Is the patient RECENTLY diagnosed with IBD (*within ~12 months)* or SUSPECTED IBD (*not yet confirmed)*? ☐ Yes ☐ No ☐ Not known

If 'Yes', is the patient willing to join the more detailed study for recently diagnosed patients?

Current IBD Diagnosis: ☐ Crohn's ☐ UC ☐IBD – unspecified (IBDU) ☐ Suspected IBD

**(Crohn's colitis should be included with 'Crohn's')*

*Date of first IBD diagnosis:
(Enter as DD/MM/YYYY format. If exact date and month not known, enter as 01/01/YYYY format) _____

Level of certainty regarding diagnosis of **IBD** ☐ 1 ☐ 2 ☐ 3
(1 = not certain; 3 = very certain)

Certainty of diagnosis **CD vs UC vs IBDU** ☐ 1 ☐ 2 ☐ 3
(1 = not certain; 3 = very certain)

Has IBD diagnosis been confirmed by a hospital specialist?

☐ Yes ☐ No ☐ Not known

Diagnostic methods *(indicate all relevant at the time of diagnosis or used subsequently):*

☐ Endoscopy ☐ Radiology ☐ Histology ☐ Surgery

☐ Other_____ ☐ Not known

Physician's global assessment of current IBD ***inflammatory*** activity *(i.e. on the day of BioResource blood sampling)*:

☐ Normal ☐ Mild ☐ Moderate ☐ Severe ☐ Not known

Applicable to newly diagnosed patients or SUSPECTED of having IBD only

Duration of symptoms prior to diagnosis:

☐ <1 month ☐ 1-6 months ☐ >6 months ☐ Not known

What has been the peak CRP (mg/l)? _____

If unknown say 'not known'

What has been the peak calprotectin (ug/g)?_____

If unknown say 'not known'

Limitations in daily activities ☐ No limitations ☐ Occasional ☐ Frequent ☐ Not known

Has the patient ever been admitted to hospital for an IBD flare?

☐ Yes ☐ No ☐ Not known

Have there been any changes in IBD diagnosis *(e.g. UC to CD)*?

☐ Yes ☐ No

Year of change in IBD diagnosis _____

Enter change in IBD diagnosis:

☐ UC to CD ☐ IBDU – type unspecified to CD

☐ CD to UC ☐ IBDU – type unspecified to UC

☐ Other_____

Please complete this section for patients diagnosed with CROHN'S disease

*Macroscopic extent (Select all that apply):
***NB** - *a frequent mistake is to assume that a patient who has had a right hemicolectomy has had colonic involvement when in fact they just had ileal disease: please be sure about this!*

NB *a bit of 'spill-over' inflammation in the caecum does not make it 'colonic'.*

☐ Oesophago-gastric ☐ Duodenal ☐ Jejunal ☐ Ileal ☐ Colonic ☐ Rectal

*Ever had perianal involvement?:
(Often not easy to find in medical notes - you may find it easier to ask the patient!)

☐ Yes ☐ No ☐ Not known

If 'Yes' - What type of perianal lesion has the patient had? *(Select all that apply):*

☐ Tags / fissures / ulcers
☐ Perianal abscess
☐ Simple fistula (single fistula, little clinical problem)
☐ Complex fistula (more than one or branching or recto-vaginal or major problem)
☐ Other _____

*Behaviour: NB Crohn's surgery is usually undertaken for a B2 or B3 complication – so do look at notes / radiol reports / op notes around time of any surgery to help classification. Even with no surgeries look at e.g. CT, MRI or barium X-ray reports for e.g. 'strictures or narrowing' (=B2) or 'mesenteric abscess / phlegmon' (=B3)

☐ B1 (inflammatory)
☐ B2 (stenosing / stricturing)
☐ B3 (*internal* penetrating* - see list below) – NB *If the only fistulae have been perianal this does not make it B3*

*If B3, Please specify the nature of the internal perforating / penetrating disease (*Select all that apply*):

☐ previous internal abscess (mesenteric abscess, intra-abdominal abscess, paracolic, pelvic etc)
☐ Entero-enteric or entero-colic fistula
☐ Entero- vesical or colo-vesical fistula (= fistula to bladder)
☐ Entero- cutaneous or colo-cutaneous fistula (= fistula to skin – but not perianal – see above)
☐ Other _____

Applicable to newly diagnosed patients or SUSPECTED of having IBD only
(If under investigation, complete both Harvey Bradshaw and Mayo colitis score but do not produce a final score)

Harvey Bradshaw

General well-being	Number of liquid stools per day	Abdo pain	Abdo mass	Extra-intestinal manifestations (score 1 for each)
0 = Well 1 = Slightly below par 2 = Poor 3 = Very poor 4 = Terrible	TOTAL = _____	0 = None 1 = Mild 2 = Moderate 3 = Severe	0 = None 1 = Dubious 2 = Definite 3 = Definite and tender	Arthralgia Uveitis Erythema nodosum Pyoderma gangrenosum Mouth ulcers Anal fissure New fistula Abscess

Current Harvey Bradshaw score (please tick/circle in table above): TOTAL = _____

Has the patient had surgery for Crohn's? ☐ Yes ☐ No ☐ Not known

	Year	What op? *(Enter number(s) from list below)*	Which hospital?
*Op1	……	……	……
*Op2	……	……	……
*Others	……	……	……

1. Colectomy and ileostomy
2. Colectomy and ileo-anal pouch
3. Defunctioning ileostomy / Colostomy
4. Drainage of intra-abdominal abscess
5. Ileal / jejunal resection
6. Ileal / jejunal stricturoplasty
7. Ileo-caecal resection (Right hemicolectomy)
8. Partial colectomy
9. Proctectomy
10. Strictureplasty
11. Insertion of seton suture
12. Drainage of perianal abscess
13. Perianal fistula repair
14. Closure of Stoma
15. Other ……

For surgeries 1, 2, 3, 5, 7, 8, 9 please answer the question below

*What was the indication for surgery?

☐ Strictures/stenosis/obstruction

☐ Internal penetration e.g. mesenteric abscess, paracolic abscess, internal fistula to bladder or skin

☐ Uncontrolled gut luminal inflammation

☐ Uncontrolled perianal Crohn's

☐ Other _____ *(please specify)*

*Does the patient currently have a stoma? ☐ Yes ☐ No ☐ Not known

Please complete this section for patients diagnosed with ULCERATIVE COLITIS OR IBD-UNCLASSIFIED (INDETERMINATE COLITIS)

*Maximum macroscopic extent **ever**:

☐ Rectum ☐ Recto-sigmoid ☐ < Splenic ☐ <Hepatic ☐ Total ☐ Unknown

Maximum macroscopic extent at **last assessment**:

☐ Rectum ☐ Recto-sigmoid ☐ < Splenic ☐ <Hepatic ☐ Total

☐ Quiescent/normal throughout ☐ Unknown

*Has the patient undergone surgical colectomy?

☐ Yes ☐ No ☐ Not known

→ *Date _____ *(If only year known, enter as 01/01/YYYY)*

→ *Indication for colectomy:

☐ Acute severe colitis ☐ Chronic continuous colitis ☐ Dysplasia ☐ Colorectal Cancer

☐ Not known

→ *Does the patient still have a rectal stump in situ?

☐ Yes ☐ No ☐ Not known

Has the patient undergone reconstructive surgery with an ileo-anal pouch?

☐ Yes ☐ No ☐ Not known

↓

Is the pouch still in place?

☐ Yes ☐ No ☐ Not known

Applicable to newly diagnosed patients or SUSPECTED of having IBD only

(If under investigation, complete both Harvey Bradshaw and Mayo but do not produce a final score)

Mayo colitis score

Stool frequency	Rectal Bleeding	Physician assessment	Endoscopic score (if available)
0 = Normal	0 = None	0 = Normal	0 = Normal / Inactive
1 = 1-2 stools per day more than normal	1 = Visible blood with stool less than half the time	1 = Mild	1 = Mild
2 = 3-4 stools per day more than normal	2 = Visible blood with stool more than half the time	2 = Moderate 3 = Severe	2 = Moderate 3 = Severe
3 = > 4 stools per day more than normal	3 = Passing blood alone		

Current Mayo score (please tick/circle in table above): TOTAL = _____

Extra intestinal manifestations and co-morbidities

For EACH please tick YES (Y) or No (N) – **Tick 'no' if patient has not been diagnosed with, and has no symptoms of, the listed conditions, the 'no's' are important! If equivocal, please tick 'Not known'.**

****If No for all please tick here**: ☐ No for all**

Primary Sclerosing Cholangitis (*incl PSC / AIH overlap, small duct PSC*):

☐ Y ☐ N ☐ Not known

Enteropathic arthritis :

☐ Y ☐ N ☐ Not known

Erythema Nodosum:

☐ Y ☐ N ☐ Not known

Iritis / uveitis (confirmed by Ophthalmology):

☐ Y ☐ N ☐ Not known

Orofacial Granulomatosis (oral Crohn's):

☐ Y ☐ N ☐ Not known

Psoriasis:

☐ Y ☐ N ☐ Not known

Ankylosing Spondylitis:

☐ Y ☐ N ☐ Not known

Multiple Sclerosis:

☐ Y ☐ N ☐ Not known

Lymphoma:

☐ Y ☐ N ☐ Not known

→ Date of diagnosis: _____

Other malignancy:

☐ Y ☐ N ☐ Not known

→ Type of malignancy: _____
Date of diagnosis: _____

Serious infections:

☐ Y ☐ N ☐ Not known

→ Infection type: (*specify e.g. TB, pneumonia*) _____
Date of diagnosis: _____

Other (extra-intestinal manifestations of IBD or other inflammatory/auto-immune diseases (separate with a comma):

_____

Treatment history – Please indicate which IBD drugs the patient has ever received:

(Complete all that apply)

Please use the chart on the next page to select an adverse event number

Treatment for IBD	Date of starting If only year known enter as 01/01/yyyy	Currently on it? Y / N / NK	Date of stopping If only year known enter as 01/01/yyyy	Was the treatment effective? 1. Yes 2. Unable to assess (unable to tolerate) 3. Unable to assess (on therapeutic dose < 4 months) 4. No (on therapeutic dose >4 months - did not work) 5. Worked for <12 months then lost response 6. Worked for >12 months then lost response 7. Not known (e.g. started anti-TNF at same time, partial response only)	Significant adverse events requiring Rx cessation or dose reduction? Y / N / NK specify number(s) from chart below
(example)	*01/01/2011*	*N*	*01/01/2011*	*2*	*Y – 13 (ALT=450), 16*
Azathioprine					
Mercaptopurine					
Methotrexate					

If this information has already been entered as part of the PRED4 study please tick ☐

What is the PRED4 identifier? (if not known, please enter 'Not known') _____

Has the patient ever been tried on low dose Thiopurine and Allopurinol ☐ Yes ☐ No ☐ Not known
(for example if developed side effects)

	Date of starting If only year known enter as 01/01/yyyy	Currently on it? Y / N / NK	Date of stopping If only year known enter as 01/01/yyyy	Was the treatment effective? 1. Yes 2. No 3. Unable to assess (e.g. had to stop due to side effects) 4. Not known	Significant adverse events? Y / N / NK specify number(s) from chart below
Ciclosporin					

	Date of starting If only year known enter as 01/01/yyyy	Currently on it? Y / N / NK	Date of stopping If only year known enter as 01/01/yyyy	Was the treatment effective? 1. Yes 2. No 3. Partial (response but not remission) 4. Unable to assess (e.g. unable to tolerate) 5. Worked for < 12 months then lost response 6. Worked for > 12 months then lost response 7. Only at high dose / increased frequency 8. Not known	Significant adverse events? Y / N / NK specify number(s) from list below
Infliximab					
Adalimumab					
Golimumab					
Vedolizumab					
Ustekinumab					

If this information has already been entered as part of the PANTS study please tick ☐

What is the PANTS identifier? (if not known, please enter 'Not known') _____

	Date of starting If only year known enter as 01/01/yyyy	**Currently on it?** Y / N / NK	**Date of stopping** If only year known enter as 01/01/yyyy	**Was the treatment effective?** 1. Yes - (remission with no other drug used) 2. Partial (response but not remission) 3. No (did not respond despite an adequate trial of therapy) 4. Unsure (e.g. not on it for long enough, started more than one drug at same time) 5. Worked for < 12 months then lost response 6. Worked for > 12 months then lost response 7. Not known	**Significant adverse events?** Y / N / NK ↓ specify number(s) from list below
Mesalazine (5 ASA)					

	Date of starting If only year known enter as 01/01/yyyy	**Currently on it?** Y / N / NK	**Date of stopping** If only year known enter as 01/01/yyyy	**Was the treatment effective?** 1. Yes 2. No 3. Initially responded then lost response 4. Unable to assess (e.g. unable to tolerate) 5. Not known	**Significant adverse events?** Y / N / NK ↓ specify number(s) from list below
Oral steroids (prednisolone or budesonide)					

	Date of starting If only year known enter as 01/01/yyyy	**Currently on it?** NA	**Date of stopping** NA	**Was the treatment effective?** 1. Yes (no 'rescue' therapy needed) 2. No (required additional rescue therapy) 3. Unable to assess (e.g. unable to tolerate) 4. Not known	**Significant adverse events?** Y / N / NK ↓ specify number(s) from list below
IV steroids					

	Date of starting If only year known enter as 01/01/yyyy	**Currently on it?** Y / N / NK	**Date of stopping** If only year known enter as 01/01/yyyy	**Was the treatment effective?** 1. Yes 2. No 3. Partial (response but not remission) 4. Not known	**Significant adverse events?** Y / N / NK ↓ specify number(s) from list below
Any other drug? (what)					

	Date of starting If only year known enter as 01/01/yyyy	**Currently on it?** Y / N / NK	**Date of stopping** If only year known enter as 01/01/yyyy	**Was the treatment effective?** **Was the treatment effective?** 1.Yes – worked at standard dose of 5mg BD 2.Yes – worked but only at higher dose e.g. 10 and 5 or 10mg BD 3. Unable to assess (unable to tolerate) 4. Unable to assess (on therapeutic dose < 4 months) 5. No (on therapeutic dose >4 months - did not work) 6. Worked for < 12 months then lost response 7. Worked for >12 months then lost response 8. Not known 9. Partial (response but not remission)	**Significant adverse events?** Y / N / NK ↓ specify number(s) from list below
Tofacitinib					
Had the patient ever had VTE before starting Tofacitinib?			□ Y	□ N	
Did they develop VTE while on Tofacitinib?			□ Y	□ N	

Please circle all the IBD treatments that the patient will be on from **today** (include all those that are being started, as well as those being continued)

Mesalazine	Oral steriods	IV steriods	Infliximab	Ciclosporin
Adalimumab	Golimumab	Azathioprine	Mercaptopurine	Methotrexate
Vedolizumab	Antibiotic	None	Ustekinumab	Other:_____

Please use the numbers in this table to complete the significant adverse events column in the treatment history tables above

Adverse Event	Adverse Event	Adverse Event
1. Abdominal pain	13. Infection a) bacterial b) viral c) TB / Tuberculosis d) Other / not known	25. Psoriasis
2. Anaemia	14. Injection site reaction	26. Psychosis
3. Anaphylaxis or anaphylactoid reaction	15. Interstitial nephritis	27. Rash
4. Could not tolerate	16. Joint pain	28. Raised lipids
5. Demyelination or other neurological symptoms	17. Leucopaenia a) Minimum white cell count b) Minimum neutrophil count	29. Renal Impairment
6. Diarrhoea	18. Malaise	30. Sepsis
7. Deranged LFTs a) Maximum ALT b) Maximum ALP c) Maximum bilirubin	19. Nasopharyngitis	31. Thrombocytopenia
8. Exacerbation of IBD symptoms	20. Nausea / vomiting	32. Other
9. Fever	21. Neutropaenia a) Minimum white cell count b) Minimum neutrophil count	33. Not known
10. Flu-like symptoms	22. Osteopenia	
11. Hypertension	23. Pancreatitis a) maximum amylase b) maximum lipase	
12. Hypotension	24. Pancytopaenia	

Applicable to newly diagnosed patients or SUSPECTED of having IBD only

Samples obtained for the IBD BioResource

Blood and stool samples requested (tick all that apply)

☐ Blood for DNA Date blood for DNA taken:_____

☐ Blood for serum Date blood for serum taken:_____

☐ Blood for PAX Date blood for PAX taken:_____

☐ Stool Date stool collected:_____

Has the patient had oral bowel prep for colonoscopy within the month prior to collecting the IBD BioResource stool sample?

☐ Yes ☐ No ☐ Not known

How many days after bowel prep was the stool sample taken? _____ *(If unknown, please enter 'Not known')*

Ileal biopsy samples obtained?

☐ Yes ☐ No ☐ Not known

☐ Visible inflammation ☐ Not inflamed

Rectal biopsies obtained?

☐ Yes ☐ No ☐ Not known

☐ Visible inflammation ☐ Not inflamed

Date Biopsies taken: _____

Health and Lifestyle questionnaire will be completed ☐ Online ☐ Paper

Demographics (*Section to be completed by research staff)*

Family history of IBD?

☐ Yes ☐ No ☐ Not known

Which relative?	Which type of IBD?*	Relative name *(if participant willing to share)?*
……	……	……
……	……	……
……	……	……

**UC, CD, IBD-type unspecified, Other, Not known*

Smoking status at *DIAGNOSIS (please tick one option):*

☐ Never smoked

☐ Not known

☐ Smoking at diagnosis:

→ Roughly how many cigarettes was the patient smoking at the time of diagnosis?

☐ Less than 5 ☐ 5+ ☐ Pipe only ☐ Not known

☐ Had quit before diagnosis:

→ Roughly how long before diagnosis did patient quit smoking?

☐ Less than 1 month ☐ 1-6 months ☐ More than 6 months ☐ Not known

CURRENT smoking status:

☐ Not smoking ☐ Smoking ☐ Not known ☐ Other _____

Has the IBD BioResource consent been signed?

***This section is a vital field for NIHR accrual data**:**

☐ Y ☐ N

Consent obtained:
□ Face to Face □ Online

Date of consent: _____

Which version of consent form has been used?:
_____

If online please specify the
E-consent reference number:
_____

Date of most recent clinic review (i.e. when were data re clinical features last updated?): _____

Has the patient withdrawn from the IBD BioResource study?

☐ Y ☐ N ☐ Not known

Withdrawal status?

☐ Withdrawn with no participation

☐ Withdrawn with no participation and data removed

☐ Deceased

☐ Other

Date withdrawal requested: _____

Date of actual withdrawal: _____

Withdrawal form ID number: _____

Withdrawn by: _____