

Legacy Indicator

Consortium ID

Check here if patient was recruited under the original CD ileal protocol:

Legacy patient

Recruitment

Meets all eligibility requirements?

- Yes
 No

(Please refer to the Eligibility and Recruitment section of the SOP to confirm that patient meets all eligibility requirements.)

Consent obtained?

- Yes
 No

Recruitment timepoint

- Pre-surgery*
 Post-surgical visit
 First post-surgical endoscopy
(* For use only by GRCs collecting surgical and/or PBMC samples)

Recruitment date:

Diet ID:

(Once a Diet ID has been obtained, please contact PSDAC to inform them that a new patient has been recruited and to provide them with the Diet ID.)

Registration And Demographics

Registration Information

Father's Consortium ID

Mother's Consortium ID

Child's Consortium ID (if parent)

Demographic and Early Childhood Information

Hispanic?

- Yes
 No
 Unknown

Jewish?

- Yes
 No
 Unknown

Is grandparent Jewish?

	Yes	No	Unknown
Paternal grandfather	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Paternal grandfather Ashkenazi?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Paternal grandmother	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Paternal grandmother Ashkenazi?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Maternal grandfather	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Maternal grandfather Ashkenazi?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Maternal grandmother	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Maternal grandmother Ashkenazi?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Race

- White
 Black/African American
 Asian
 American Indian/Alaskan Native
 Native Hawaiian/Pacific Islander
 Unknown
 Other (specify below)

Specify race:

Birth order

- 1st
 2nd
 3rd
 4th
 5th
 6th
 >6th
 Unknown

Breast fed?

- Yes
 No
 Unknown

Duration of breastfeeding (months):

Age at weaning (months):

Family History of IBD

	CD	UC/IC	IBD affected (type unclear)	Unaffected	Unknown
Father	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mother	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Check here if no siblings:

 No siblings

Number of siblings with CD:

Number of siblings with UC/IC:

Number of siblings who are IBD affected (type unclear):

Number of siblings unaffected:

Number of siblings with unknown IBD status:

Check here if no children:

 No children

Number of children with CD:

Number of children with UC/IC:

Number of children who are IBD affected (type unclear):

Number of children unaffected:

Number of children with unknown IBD status:

Family history of IBD in 2nd degree relatives?

- Yes
 No
 Unknown

Indicate family type:

- CD
 UC
 Mixed
 Unknown

Smoking Status at Diagnosis

Smoking status at diagnosis:

- Yes
 Ex-smoker
 No
 Unknown

Smoking Status at Time of Index Surgery

Smoking status at time of index surgery:

- Yes
 Ex-smoker
 No
 Unknown

Year started smoking:

Year stopped smoking:

Number of cigarettes per day (1 pack = 20 cigarettes):

Check here if number of cigarettes per day is unknown:

- Unknown

BMI at Time of Recruitment

Height:

Height unit:

- inches
 centimeters

If height is unknown, please check this box:

- Height unknown

Weight:

Weight unit:

- pounds
 kg

If weight is unknown, please check this box:

Weight unknown

Smoking status (at time of recruitment, migrated from original study)

Current smoker
 Ex-smoker
 Non-smoker
 Unknown

Year started smoking (at time of recruitment, migrated from original study)

_____ (YYYY)

Year stopped smoking (at time of recruitment, migrated from original study)

_____ (YYYY)

Number of cigarettes per day (at time of recruitment, migrated from original study)

_____ ((1 pack = 20 cigarettes))

Please check this box if the number of cigarettes per day is unknown (at time of recruitment, migrated from original study)

Unknown

Operative and Pathology Reports

Date of index resectional surgery:

Pre-operative Imaging Report(s)

Note that these upload fields are for imaging REPORTS, but not for the images themselves.

Date of imaging report

Type of imaging

- MR
 CT
 Other

Upload an anonymized copy of the imaging report

Date of imaging report

Type of imaging

- MR
 CT
 Other

Upload an anonymized copy of the imaging report

Date of imaging report

Type of imaging

- MR
 CT
 Other

Upload an anonymized copy of the imaging report

Operative and Pathology Report Uploads

Upload an anonymized copy of the operative report

Upload an anonymized copy of the pathology report

Operative or pathology report uploaded in old study

Operative or pathology report uploaded in old study

Operative or pathology report uploaded in old study

Operative or pathology report uploaded in old study

Operative and Pathology Report Review

Date of operative report

(MM-DD-YYYY)

Findings at surgery based on operative and pathology reports. Check all that apply. Pathology findings trump operative findings.

- Stricture
- Fistula
- Abscess
- None of the above
- Unknown

Other procedures performed during ileal resectional surgery

- Separate additional small bowel resection
- Strictureplasty
- Separate colonic resection
- Unknown
- Other

Type of anastomosis

- End-to-end
- Side-to-side
- End-to-side
- Unknown

Anastomosis hand-sewn or stapled?

- Hand-sewn
- Stapled
- Unknown

Length of resection

Check here if resection length is unknown

- Length unknown

Appendix present?

- Yes
- No
- Unknown

Proximal surgical margin free of gross inflammation?

- Yes
- No
- Unknown

Granulomas?

- Yes
- No
- Unknown

Endoscopy

Date of endoscopy: _____

Was endoscopy performed on site or off site?

- On site
 Off site

Mucosal appearance of neo-terminal ileum at endoscopy (Rutgeerts Score):

- i0: No lesions in the distal ileum (Normal)
 i1: 5 or fewer aphthous ulcers in the distal ileum
 i2a: lesions confined to the ileocolonic anastomosis (including anastomotic stenosis)
 i2b: more than 5 aphthous ulcers or larger lesions, with normal mucosa in-between, in the neoterminal ileum (with or without anastomotic lesions)
 i3: Diffuse aphthous ileitis with diffusely inflamed mucosa
 i4: Large ulcers with diffuse mucosal inflammation or nodules or stenosis in the neoterminal ileum
 Unknown

Rutgeerts i2 entered in old project

- Rutgeerts i2

Report Uploads

Upload an anonymized copy of the ENDOSCOPY report, including a detailed description of any abnormalities in the colon.

(For redaction instructions, see section of SOP entitled "Redaction of PHI From Uploaded Documents.")

Endoscopy reported uploaded in old study

- Endoscopy report uploaded in old study

Upload an anonymized copy of the PATHOLOGY report.

(For redaction instructions, see section of SOP entitled "Redaction of PHI From Uploaded Documents.")

Pathology report uploaded in old study

- Pathology reported uploaded in old study

Was a video of the endoscopy obtained?

- Yes
 No
 (Store videos locally until further instructed.)

Intestinal Biopsies

Was the neo-terminal ileum intubated with ≥ 10 cm of ileum visualized?

- Yes
 No
 Unknown

If no, was it due to:

- Anastomotic stricture
 Non-anastomotic stricture
 Other reason (specify)
 Unknown

Other reason:

Were biopsies taken 5-10cm proximal to the anastomosis?

- Yes
 No
 Unknown

Was a video of the ileocecal region obtained?

- Yes
 No
(If Yes, store video locally until further notice.)

Terminal Ileum Biopsies (taken 5-10cm proximal to the anastomosis in the neo-terminal ileum)

Number of RNAlater tubes
(1 bite per tube)

- 0
 1
 2

RNAlater tube 1 ID:

((ID from barcode label, starting with SB))

RNAlater tube 2 ID:

((ID from barcode label, starting with SB))

Number of microbial DNA tubes
(1 bite per tube)

- 0
 1
 2

Microbial DNA tube 1 ID:

((ID from barcode label, starting with SB))

Microbial DNA tube 2 ID:

((ID from barcode label, starting with SB))

Biopsies sent to pathology?

- Yes
 No
 Unknown

If no, biopsies for histology (x2):

- None
 1
 2

Histology biopsy 1 ID:

((from barcode label))

Colonic biopsies (taken 10 cm distal to the anastomosis)

Number of RNAlater tubes
(1 bite per tube) 0
 1
 2

RNAlater tube 1 ID:

((ID from barcode label, starting with SB))

RNAlater tube 2 ID:

((ID from barcode label, starting with SB))

Number of microbial DNA tubes
(1 bite per tube) 0
 1
 2

Microbial DNA tube 1 ID:

((ID from barcode label, starting with SB))

Microbial DNA tube 2 ID:

((ID from barcode label, starting with SB))

Biopsies sent to pathology? Yes
 No
 Unknown

If no, biopsies for histology (x2): None
 1
 2

Histology biopsy 1 ID:

((from barcode label))

Rectum sigmoid biopsies (taken 20 cm from the anal verge)

Number of RNAlater tubes
(1 bite per tube) 0
 1
 2

RNAlater tube 1 ID:

((ID from barcode label, starting with SB))

RNAlater tube 2 ID:

((ID from barcode label, starting with SB))

Number of microbial DNA tubes
(1 bite per tube) 0
 1
 2

Microbial DNA tube 1 ID:

((ID from barcode label, starting with SB))

Microbial DNA tube 2 ID:

((ID from barcode label, starting with SB))

Biopsies sent to pathology?

- Yes
 No
 Unknown

If no, biopsies for histology (x2):

- None
 1
 2

Histology biopsy 1 ID:

((from barcode label))

Blood Collection

Check here if patient was recruited at first endoscopy (and you have completed the Blood Collection form in the Recruitment Event).

Patient recruited at first endoscopy

If you check this box and have completed the Blood Collection form in the Recruitment Event, do not complete this form again here.

Was blood sample collected prior to the administration of anesthesia?

Yes
 No
 Unknown

Date samples drawn:

Is this the first blood sample being obtained from this patient for this study?

Yes
 No

DNA: Shipped to Feinstein

((from barcode label))

DNA: Stored locally

((from barcode label))

PAXgene: Shipped to Feinstein

((from barcode label))

PAXgene: Stored locally

((from barcode label))

Serum aliquots (stored locally)

Serum aliquot 1

((from barcode label))

Volume

125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 2

((from barcode label))

Volume 125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 3

((from barcode label))

Volume 125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 4

((from barcode label))

Volume 125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 5

((from barcode label))

Volume 125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 6

((from barcode label))

Volume 125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 7

((from barcode label))

Volume

- 125 ul
- 250 ul
- 500 ul
- other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 8

((from barcode label))

Volume

- 125 ul
- 250 ul
- 500 ul
- other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 9

((from barcode label))

Volume

- 125 ul
- 250 ul
- 500 ul
- other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 10

((from barcode label))

Volume

- 125 ul
- 250 ul
- 500 ul
- other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 11

((from barcode label))

Volume

- 125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 12

((from barcode label))

Volume

- 125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 13

((from barcode label))

Volume

- 125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 14

((from barcode label))

Volume

- 125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 15

((from barcode label))

Volume 125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 16

((from barcode label))

Volume 125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 17

((from barcode label))

Volume 125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 18

((from barcode label))

Volume 125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 19

((from barcode label))

Volume 125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

_____ (ul)

Serum aliquot 20

_____ ((from barcode label))

Volume

- 125 ul
- 250 ul
- 500 ul
- other volume (specify below)

Specify other volume (ul)

_____ (ul)

Serum aliquot 21

_____ ((from barcode label))

Volume

- 125 ul
- 250 ul
- 500 ul
- other volume (specify below)

Specify other volume (ul)

_____ (ul)

Serum aliquot 22

_____ ((from barcode label))

Volume

- 125 ul
- 250 ul
- 500 ul
- other volume (specify below)

Specify other volume (ul)

_____ (ul)

Serum aliquot 23

_____ ((from barcode label))

Volume

- 125 ul
- 250 ul
- 500 ul
- other volume (specify below)

Specify other volume (ul)

_____ (ul)

Serum aliquot 24

((from barcode label))

Volume

- 125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 25

((from barcode label))

Volume

- 125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 26

((from barcode label))

Volume

- 125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 27

((from barcode label))

Volume

- 125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

(ul)

Serum aliquot 28

((from barcode label))

Volume 125 ul
 250 ul
 500 ul
 other volume (specify below)

Specify other volume (ul)

_____ (ul)

CBC with differential

Was CBC obtained? Yes
 No

Was CBC completed on the same date blood samples were drawn ("Date samples drawn" above)? Yes
 No

If "No," when was CBC collected?

Please explain why CBC was not obtained:

Upload an anonymized copy of the CBC report.

(For redaction instructions, see section of SOP entitled "Redaction of PHI From Uploaded Documents.")

CBC report uploaded in old study CBC report uploaded in old study

Disease Location and EIMs

Latest clinical exam/encounter migrated from original study _____

Macroscopic disease location at time of recruitment ([recruit_date])

Note: This would include the ileocolonic disease that was present prior to the surgery, any findings at the time of surgery, and any new disease since then.

	Yes	No	Unknown
Esophagus:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Stomach:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Duodenum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Upper GI (legacy field):	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Jejunum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Proximal ileum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Distal ileum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Terminal ileum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ileal (legacy field):	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cecum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Colon (not including cecum or rectum):	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Rectum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Colorectal (legacy field):	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Perianal/Perineal:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Disease behavior at time of recruitment ([recruit_date])

Note that this refers to the maximal disease behavior since diagnosis.

CD disease behavior: B1
 B2
 B3
 Unknown

Extra-Intestinal Manifestations: Joints

	Yes	No	Unknown
Large joint related to disease activity:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Small joint unrelated to disease activity:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ankylosing spondylitis:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sacro-iliitis:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Non-specific joint inflammation:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Extra-Intestinal Manifestations: Skin

	Yes	No	Unknown
Erythema nodosum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pyoderma:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Extra-Intestinal Manifestations: Eyes

	Yes	No	Unknown
Uveitis:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Episcleritis:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Undiagnosed ocular inflammation:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Extra-Intestinal Manifestations: Liver

	Yes	No	Unknown
Primary sclerosing cholangitis:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Treatment Prior To Index Surgery

Year in which a definitive diagnosis of IBD was made

(YYYY)

Note: All items on this form refer to the period BEFORE the index resectional surgery.

Surgical Treatment and Hospitalizations Prior to Index Resectional Surgery

Surgery for complication or treatment of CD: Yes
 No
 Unknown

	Yes	No	Unknown
Small bowel resection:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Large bowel resection:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Strictureplasty:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bowel resection/strictureplasty:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Diversion:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Permanent stoma:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Gastroenterostomy:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Abdominal fistula/abscess:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Perineal fistula/abscess:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Surgery for dysplasia/cancer:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date of first operation (for treatment of IBD):

(MM/YYYY)

If date of first operation is unknown, please check this box: Unknown

Was the operation for abdominal disease (e.g., resection, strictureplasty, abscess drainage) or perineal disease (including diversions)? Abdominal disease
 Perineal disease

Date of second operation (for treatment of IBD):

(MM/YYYY)

If date of second operation is unknown, please check this box: Unknown

Was the operation for abdominal disease (e.g., resection, strictureplasty, abscess drainage) or perineal disease (including diversions)? Abdominal disease
 Perineal disease

Most recent surgery date migrated from old study

Total number of abdominal surgeries (migrated from original study) _____

If number of operations for abdominal disease is unknown, please check this box (migrated from original study).

Unknown

Total number of perineal surgeries (migrated from original study) _____

If number of operations for perineal disease is unknown, please check this box (migrated from original study).

Unknown

Diagnosis of dysplasia/cancer (colorectal):

Yes
 No
 Unknown

If yes, year: _____

If year is unknown, please check this box:

Unknown

Appendectomy:

Yes
 No
 Unknown

If yes, year: _____

If year is unknown, please check this box:

Unknown

Hospitalizations since last assessment (for treatment of IBD):

0
 1
 2 or more
 Unknown

Medical Therapy Prior to Index Resection Surgery for Treatment of Crohn's Disease

Aminosalicylates used since diagnosis?

Yes
 No
 Unknown

Aminosalicylates used within 3 months prior to index surgery?

Yes
 No
 Unknown

Aminosalicylates used up to time of surgery?

Yes
 No
 Unknown

Aminosalicylates used currently (migrated from original study)

Yes
 No
 Unknown

Oral corticosteroids used since diagnosis?

Yes
 No
 Unknown

Oral corticosteroids used within 3 months prior to index surgery?

Yes
 No
 Unknown

Oral corticosteroids used up to time of surgery?

Yes
 No
 Unknown

Oral corticosteroids used currently (migrated from original study)?

Yes
 No
 Unknown

IV corticosteroids used since diagnosis?

Yes
 No
 Unknown

IV corticosteroids used within 3 months prior to index surgery?

Yes
 No
 Unknown

IV corticosteroids used up to time of surgery?

Yes
 No
 Unknown

IV corticosteroids used currently (migrated from original study)?

Yes
 No
 Unknown

Antibiotics used since diagnosis?

Yes
 No
 Unknown

Antibiotics used within 3 months prior to index surgery?

Yes
 No
 Unknown

Antibiotics used up to time of surgery?

Yes
 No
 Unknown

Antibiotics used currently (migrated from original study)?

Yes
 No
 Unknown

Immunomodulatory drugs used since diagnosis?

Yes
 No
 Unknown

Immunomodulatory drugs used within one year prior to index surgery?

Yes
 No
 Unknown

Immunomodulatory drugs used within 3 months prior to index surgery? Yes
 No
 Unknown

Immunomodulatory drugs used up to time of surgery? Yes
 No
 Unknown

Immunomodulatory drugs used currently (migrated from original study)? Yes
 No
 Unknown

MTX used since diagnosis? Yes
 No
 Unknown

MTX used with one year prior to index surgery? Yes
 No
 Unknown

MTX used within 3 months prior to index surgery? Yes
 No
 Unknown

MTX used up to time of surgery? Yes
 No
 Unknown

MTX used currently (migrated from original study)? Yes
 No
 Unknown

Enteral nutrition used since diagnosis? Yes
 No
 Unknown

Enteral nutrition used within 3 months prior to index surgery? Yes
 No
 Unknown

Enteral nutrition used up to time of surgery? Yes
 No
 Unknown

Enteral nutrition used currently (migrated from original study)? Yes
 No
 Unknown

Anti-TNF used since diagnosis (migrated from original study)? Yes
 No
 Unknown

Anti-TNF used currently (migrated from original study)? Yes
 No
 Unknown

Infliximab used since diagnosis? Yes
 No
 Unknown

Infliximab used within 1 year prior to index surgery? Yes
 No
 Unknown

Have you completed induction dosing (infliximab)? Yes
 No

Maximal maintenance dose of infliximab per kg bodyweight (mg/kg) during 1 year prior to surgery _____

Shortest maintenance dosing interval during 1 year prior to surgery (infliximab)? _____
 (Every ___ weeks)

Every [enter number] weeks

Was infliximab taken in combination with azathioprine, 6-MP, or methotrexate at any time in the one year prior to surgery for 8 weeks or longer? Yes
 No
 Unknown

Indicate which drug was taken in combination with infliximab at any time one year prior to surgery (for 8 weeks or longer). Check all that apply. Azathioprine
 6-MP
 Methotrexate

Was therapeutic drug monitoring (TDM) performed for infliximab in the one year prior to surgery? (Do not include TDM obtained during treatment induction.) Yes
 No
 Unknown

Assay type Prometheus
 Labcorp
 Quest
 Mayo
 Other
 Unknown

Specify assay type _____

Was this a trough level (i.e., drawn within week prior to infusion)? Yes
 No
 Unknown

Drug level (mcg/mL) _____
 (mcg/mL)

Enter antibody level (AU/mL): _____
 (AU/mL)

Infliximab used within 3 months prior to index surgery? Yes
 No
 Unknown

Date started:

(MM/YYYY)

Date of last dose prior to surgery:

(MM/YYYY)

Most recent dose and schedule:

- *Induction* 5 mg/kg IV at 0, 2, and 6 weeks
 5 mg/kg IV every 4 weeks
 5 mg/kg IV every 6 weeks
 5 mg/kg IV every 8 weeks
 7.5 mg/kg IV every 4 weeks
 7.5 mg/kg IV every 6 weeks
 7.5 mg/kg IV every 8 weeks
 10 mg/kg IV every 4 weeks
 10 mg/kg IV every 6 weeks
 10 mg/kg IV every 8 weeks
 Other dose and schedule

Describe other dose and schedule:

Adalimumab used since diagnosis?

- Yes
 No
 Unknown

Adalimumab (Humira) used within 1 year prior to surgery?

- Yes
 No
 Unknown

Have you completed induction dosing (adalimumab)?

- Yes
 No

Maximal maintenance dose during 1 year prior to surgery:

- 40 mg
 80 mg

Shortest maintenance dosing interval during 1 year prior to surgery (adalimumab)?

- Every 1 week
 Every 2 weeks
 Other interval (specify below)

Specify other dosing interval (adalimumab)

Was adalimumab taken in combination with azathioprine, 6-MP, or methotrexate at any time in the one year prior to surgery for 8 weeks or longer?

- Yes
 No
 Unknown

Indicate which drug was taken in combination with adalimumab at any time one year prior to surgery (for 8 weeks or longer). Check all that apply.

- Azathioprine
 6-MP
 Methotrexate

Was therapeutic drug monitoring (TDM) performed for adalimumab in the one year prior to surgery? (Do not include TDM obtained during treatment induction.)

- Yes
 No
 Unknown

Assay type

- Prometheus
- Labcorp
- Quest
- Mayo
- Other
- Unknown

Specific assay type

Was this a trough level (i.e., drawn within 72 hours prior to injection)?

- Yes
- No
- Unknown

Drug level (mcg/mL)

(mcg/mL)

Enter antibody level (AU/mL):

(AU/mL)

Adalimumab used within 3 months prior to index surgery?

- Yes
- No
- Unknown

Date started:

(MM/YYYY)

Date of last dose prior to surgery:

(MM/YYYY)

Most recent dose and schedule:

- *Induction* 160 mg sc at week 0, 80 mg at week 2
- 40 mg sc every 1 week
- 40 mg sc every 2 weeks
- 80 mg sc every 2 weeks
- Other dose and schedule

Describe other dose and schedule:

Certolizumab used since diagnosis?

- Yes
- No
- Unknown

Certolizumab (Cimizia) used within 1 year prior to surgery?

- Yes
- No
- Unknown

Have you completed induction dosing (certolizumab)?

- Yes
- No

Maximal maintenance dose during 1 year prior to surgery:

- 200 mg
- 400 mg

Shortest maintenance dosing interval during 1 year prior to surgery (certolizumab)?

- Every 2 weeks
 Every 4 weeks
 Other interval (specify below)

Specify other dosing interval

Was certolizumab taken in combination with azathioprine, 6-MP, or methotrexate at any time in the one year prior to surgery for 8 weeks or longer?

- Yes
 No
 Unknown

Indicate which drug was taken in combination with certolizumab at any time one year prior to surgery (for 8 weeks or longer). Check all that apply.

- Azathioprine
 6-MP
 Methotrexate

Was therapeutic drug monitoring (TDM) performed for certolizumab in the one year prior to surgery? (Do not include TDM obtained during treatment induction.)

- Yes
 No
 Unknown

Assay type

- Prometheus
 Labcorp
 Quest
 Mayo
 Other
 Unknown

Specify assay type

Was this a trough level (i.e., drawn within 72 hours of injection)?

- Yes
 No
 Unknown

Drug level (mcg/mL)

(mcg/mL)

Enter antibody level (AU/mL):

(AU/mL)

Certolizumab used within 3 months prior to index surgery?

- Yes
 No
 Unknown

Date started:

(MM/YYYY)

Date of last dose prior to surgery:

(MM/YYYY)

Most recent dose and schedule:

Induction 400mg sc at weeks 0, 2, and 4
 200mg sc every 2 weeks
 400mg sc every 2 weeks
 400mg sc every 4 weeks
 Other dose and schedule

Describe other dose and schedule:

Vedolizumab used since diagnosis?

Yes
 No
 Unknown

Vedolizumab used within 1 year prior to surgery?

Yes
 No
 Unknown

Have you completed induction dosing (vedolizumab)?

Yes
 No

Shortest maintenance dosing interval during 1 year prior to surgery (vedolizumab)

300 mg every 4 weeks
 300 mg every 8 weeks
 Other (specify below)

Specify other dosing interval (vedolizumab)

Was vedolizumab taken in combination with azathioprine, 6-MP, or methotrexate at any time in the one year prior to surgery for 8 weeks or longer?

Yes
 No
 Unknown

Indicate which drug was taken in combination with vedolizumab at any time one year prior to surgery (for 8 weeks or longer). Check all that apply.

Azathioprine
 6-MP
 Methotrexate

Was therapeutic drug monitoring (TDM) performed for vedolizumab in the one year prior to surgery? (Do not include TDM obtained during treatment induction.)

Yes
 No
 Unknown

Assay type

Prometheus
 Labcorp
 Quest
 Mayo
 Other
 Unknown

Specify assay type

Was this a trough level (i.e., within 1 week prior to dose)?

Yes
 No
 Unknown

Drug level (ug/mL)

(ug/mL)

Enter antibody level (U/mL):

(U/mL)

Vedolizumab used within 3 months prior to index surgery?

- Yes
 No
 Unknown

Date started:

(MM/YYYY)

Date of last dose prior to surgery:

(MM/YYYY)

Most recent dose and schedule:

- *Induction* 300mg IV at 0, 2, and 6 weeks
 300mg IV every 4 weeks
 300mg IV every 6 weeks
 300mg IV every 8 weeks
 Other dose and schedule

Describe other dose and schedule:

Ustekinumab used since diagnosis?

- Yes
 No
 Unknown

Ustekinumab used within 1 year prior to surgery?

- Yes
 No
 Unknown

Have you completed induction dosing?

- Yes
 No

Shortest maintenance dosing interval during 1 year prior to surgery (ustekinumab)

- 90 mg every 4 weeks
 90 mg every 8 weeks
 Other (specify below)

Specify other dosing interval (ustekinumab)

Was ustekinumab taken in combination with azathioprine, 6-MP, or methotrexate at any time in the one year prior to surgery for 8 weeks or longer?

- Yes
 No
 Unknown

Indicate which drug was taken in combination with ustekinumab at any time one year prior to surgery (for 8 weeks or longer). Check all that apply.

- Azathioprine
 6-MP
 Methotrexate

Was therapeutic drug monitoring (TDM) performed for ustekinumab in the one year prior to surgery? (Do not include TDM obtained during treatment induction.)

- Yes
 No
 Unknown

Assay type

- Prometheus
- Labcorp
- Quest
- Mayo
- Other
- Unknown

Specify assay type

Was this a trough level (i.e., within 1 week prior to dose)?

- Yes
- No
- Unknown

Drug level (ug/mL)

(ug/mL)

Enter antibody level (U/mL)

(U/mL)

Ustekinumab used within 3 months prior to index surgery?

- Yes
- No
- Unknown

Date started:

(MM/YYYY)

Date of last dose prior to surgery:

(MM/YYYY)

Most recent dose and schedule:

- *Induction* weight-based IV dose at week 0
- 90mg sc every 4 weeks
- 90mg sc every 6 weeks
- 90mg sc every 8 weeks
- Other dose and schedule

Describe other dose and schedule:

NSAIDS used since diagnosis?

- Yes
- No
- Unknown

NSAIDS used within 3 months prior to index surgery?

- Yes
- No
- Unknown

NSAIDS used up to time of surgery?

- Yes
- No
- Unknown

Most recent schedule:

- Daily
 Weekly
 Monthly
 Less than once per month
-

Probiotics used since diagnosis?

- Yes
 No
 Unknown
-

Probiotics used within 3 months prior to index surgery?

- Yes
 No
 Unknown
-

Probiotics used up to time of surgery?

- Yes
 No
 Unknown
-

Other biological therapies used since diagnosis?

- Yes
 No
 Unknown
-

Other biological therapies used within 3 months prior to index surgery?

- Yes
 No
 Unknown
-

Other biological therapies used up to time of surgery?

- Yes
 No
 Unknown
-

Other biological therapies used currently (migrated from original study)?

- Yes
 No
 Unknown
-

Specify type of other biological therapy:

Specify type of other biological therapy (migrated from original study)

Surgical Specimens Form

Uninvolved ileal margin

Number of RNAlater tubes: None
 1
 2

0.5 cm in RNAlater 1:

((from barcode label))

0.5cm in RNAlater 2:

((from barcode label))

Number of quadrant tubes (not including myofibroblast sample sent to Kuemmerle Lab): None
 1
 2
 3

Quadrants in empty tubes 1:

((from barcode label))

Quadrants in empty tubes 2:

((from barcode label))

Quadrants in empty tubes 3:

((from barcode label))

Myofibroblast sample ID:

Uninvolved colonic margin

Number of RNAlater tubes: None
 1
 2

0.5 cm in RNAlater 1:

((from barcode label))

0.5 cm in RNAlater 2:

((from barcode label))

Number of quadrant tubes (not including myofibroblast sample sent to Kuemmerle Lab): None
 1
 2
 3

Quadrants in empty tubes 1:

((from barcode label))

Quadrants in empty tubes 2:

((from barcode label))

Quadrants in empty tubes 3:

((from barcode label))

Myofibroblast sample ID:

Involved ileum

Number of RNAlater tubes:

- None
 1
 2

0.5 cm in RNAlater 1:

((from barcode label))

0.5 cm in RNAlater 2:

((from barcode label))

Number of quadrant tubes (not including myofibroblast sample sent to Kuemmerle Lab):

- None
 1
 2
 3

Quadrants in empty tubes 1:

((from barcode label))

Quadrants in empty tubes 2:

((from barcode label))

Quadrants in empty tubes 3:

((from barcode label))

Myofibroblast sample ID:

Involved colon (optional)

Number of RNAlater tubes: None
 1
 2

0.5 cm in RNAlater 1:

((from barcode label))

0.5 cm in RNAlater 2:

((from barcode label))

Number of quadrant tubes (not including myofibroblast sample sent to Kuemmerle Lab): None
 1
 2
 3

Quadrants in empty tubes 1:

((from barcode label))

Quadrants in empty tubes 2:

((from barcode label))

Quadrants in empty tubes 3:

((from barcode label))

Myofibroblast sample ID:

Mesenteric fat

Number of RNAlater tubes: None
 1
 2

0.5 cm in RNAlater 1:

((from barcode label))

0.5 cm in RNAlater 2:

((from barcode label))

Number of quadrant tubes (not including myofibroblast sample sent to Kuemmerle Lab): None
 1
 2
 3

Quadrants in empty tubes 1:

((from barcode label))

Quadrants in empty tubes 2:

((from barcode label))

Quadrants in empty tubes 3:

((from barcode label))

Myofibroblast sample ID:

PBMC Samples

Samples should be collected at endoscopy ONLY if samples were collected at recruitment.

Date samples collected:

PBMC 1:

((from barcode label))

PBMC 2:

((from barcode label))

Disease Location and EIMs Update

Use migrated information from original REDCap project

Use migrated information

Note: If patient was recruited at first endoscopy, check here and complete Disease Location and EIMs form in the Recruitment event. Do not complete this form if patient was recruited at first endoscopy.

Patient was recruited at first endoscopy

Is there evidence of disease in new locations since surgery or previous endoscopy (whichever is most recent)?

Yes
 No

Macroscopic Disease Location Since Time of Last Assessment (i.e., surgery or previous endoscopy)

	New disease	Unchanged	Unknown
Esophagus:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Stomach:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Duodenum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Jejunum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Proximal ileum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Distal ileum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Terminal ileum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cecum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Colon (not including cecum or rectum):	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Rectum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Perianal/Perineal:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Macroscopic Disease Location At Endoscopy (from original REDCap project)

	Yes	No	Unknown
Esophagus:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Stomach:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Duodenum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Jejunum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Proximal ileum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Distal ileum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Terminal ileum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cecum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Colon (not including cecum or rectum):	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Rectum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Perianal/perineal:

Maximal Disease Behavior

CD disease behavior: B1
 B2
 B3
 Unknown

CD disease behavior at endoscopy B1
 B2
 B3
 Unknown

Extra-Intestinal Manifestations Since Time of Last Assessment

Is there evidence of new extra-intestinal manifestations since surgery or previous endoscopy (whichever is most recent)? Yes
 No

Extra-Intestinal Manifestations: Joints

	New EIM	Unchanged	Unknown
Large joint related to disease activity:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Small joint unrelated to disease activity:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ankylosing spondylitis:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sacro-iliitis:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Non-specific joint inflammation:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Extra-Intestinal Manifestations At Endoscopy (from original REDCap project): Joints

	Yes	No	Unknown
Large joint related to disease activity:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Small joint unrelated to disease activity:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ankylosing spondylitis:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sacro-iliitis:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Non-specific joint inflammation:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Extra-Intestinal Manifestations: Skin

	New EIM	Unchanged	Unknown
Erythema nodosum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pyoderma:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Extra-Intestinal Manifestations At Endoscopy (from original REDCap project): Skin

	Yes	No	Unknown
Erythema nodosum:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pyoderma:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Extra-Intestinal Manifestations: Eyes

	New EIM	Unchanged	Unknown
Uveitis:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Episcleritis:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Undiagnosed ocular inflammation:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Extra-Intestinal Manifestations At Endoscopy (from original REDCap project): Eyes

	Yes	No	Unknown
Uveitis:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Episcleritis:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Undiagnosed ocular inflammation:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Extra-Intestinal Manifestations: Liver

	New EIM	Unchanged	Unknown
Primary sclerosing cholangitis:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Extra-Intestinal Manifestations At Endoscopy (from original REDCap project): Liver

	Yes	No	Unknown
Primary Sclerosing cholangitis:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Treatment Update and Disease Activity

IMPORTANT: This form is intended to capture changes from previous information; i.e., since index resectional surgery or previous endoscopy, whichever is most recent.

Date of ileal resection or previous endoscopy, whichever is most recent: _____

Surgical History Update (since last assessment on [prev_assess_date])

Did patient have surgery for complications or treatment of CD since last assessment on [prev_assess_date]?
 Yes
 No
 Unknown

	Yes	No	Unknown
Small bowel resection:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Large bowel resection:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Strictureplasty:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Diversion:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Permanent stoma:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Gastroenterostomy:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Abdominal fistula/abscess:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Perineal fistula/abscess:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Surgery for dysplasia/cancer:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date of first operation (for treatment of IBD) since last assessment on [prev_assess_date]: _____

(MM/YYYY)

If date of first operation is unknown, please check this box:

Unknown

Was the operation for abdominal disease (e.g., resection, strictureplasty, abscess drainage), perineal disease (including diversions), or post-surgical complications?

Abdominal disease
 Perineal disease
 Post-surgical complications

Date of second operation (for treatment of IBD) since last assessment on [prev_assess_date]: _____

(MM/YYYY)

If date of second operation is unknown, please check this box:

Unknown

Was the operation for abdominal disease (e.g., resection, strictureplasty, abscess drainage), perineal disease (including diversions), or post-surgical complications?

Abdominal disease
 Perineal disease
 Post-surgical complications

Date of third operation (for treatment of IBD) since last assessment on [prev_assess_date]: _____

(MM/YYYY)

If date of third operation is unknown, please check this box:

Unknown

Was the operation for abdominal disease (e.g., resection, strictureplasty, abscess drainage), perineal disease (including diversions), or post-surgical complications?

Abdominal disease
 Perineal disease
 Post-surgical complications

Diagnosis of dysplasia/cancer (colorectal) since last assessment on [prev_assess_date]?

Yes
 No
 Unknown

If yes to diagnosis of dysplasia/cancer (colorectal), month/year of diagnosis:

_____ (MM/YYYY)

If date is unknown, please check this box:

Unknown

If yes to diagnosis of dysplasia/cancer (colorectal), year of diagnosis (from original REDCap project):

_____ (YYYY)

If year is unknown, please check this box (from original REDCap project):

Unknown

Appendectomy since last assessment on [prev_assess_date]?

Yes
 No
 Unknown

If yes to appendectomy, month/year of procedure:

_____ (MM/YYYY)

If date is unknown, please check this box:

Unknown

If yes to appendectomy, year of procedure (from original REDCap project):

_____ (YYYY)

If year is unknown, please check this box (from original REDCap project):

Unknown

CD disease behavior:

Normal/Remission
 B1
 B2
 B3
 Unknown

Disease Activity and Treatment, including Harvey-Bradshaw Index (since last assessment on [prev_assess_date])

Hospitalizations (for treatment of IBD) since last assessment on [prev_assess_date]:

0
 1
 2 or more
 Unknown

Physician global appraisal of disease activity since last assessment on [prev_assess_date]:

Continuously quiescent
 Mild with remissions
 Mild but chronically active
 Moderate or severe exacerbations but remissions
 Chronically active moderate/severe disease
 Unknown

Current disease activity:

Normal/Remission
 Mild
 Moderate
 Severe
 Unknown

Subject's general well-being:

Very well
 Slightly below par
 Poor
 Very poor
 Terrible
 Unknown
 (Note: Items from Harvey-Bradshaw Index refer to subject's current condition)

Abdominal pain:

None
 Mild
 Moderate
 Severe
 Unknown
 (Note: Items from Harvey-Bradshaw Index refer to subject's current condition)

Number of liquid stools per day:

(Note: Items from Harvey-Bradshaw Index refer to subject's current condition)

If number of liquid stools/day is unknown, please check this box: Unknown

Abdominal mass:

None
 Dubious
 Definite
 Definite and tender
 Unknown
 (Note: Items from Harvey-Bradshaw Index refer to subject's current condition)

Complications: Items below from HBI refer to patient's current condition.

	Yes	No	Unknown
Aphthous ulcers:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Anal fissure:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
New fistula:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Abscess:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Medical Therapy Used Since Last Assessment (i.e., index resectional surgery or previous endoscopy, whichever is most recent) for Treatment of Crohn's Disease

Note: Do not include medications used during the first 4 weeks post-surgery or those used to treat surgical complications.

Aminosalicylates used since last assessment? Yes
 No
 Unknown

Aminosalicylates used currently? Yes
 No
 Unknown

Oral corticosteroids used since last assessment? Yes
 No
 Unknown

Oral corticosteroids used currently? Yes
 No
 Unknown

IV corticosteroids used since last assessment? Yes
 No
 Unknown

IV corticosteroids used currently? Yes
 No
 Unknown

Antibiotics used since last assessment? Yes
 No
 Unknown

Antibiotics used currently? Yes
 No
 Unknown

Immunomodulatory drugs used since last assessment? Yes
 No
 Unknown

Immunomodulatory drugs used currently? Yes
 No
 Unknown

MTX used since last assessment?

Yes
 No
 Unknown

MTX used currently?

Yes
 No
 Unknown

Enteral nutrition used since last assessment?

Yes
 No
 Unknown

Enteral nutrition used currently?

Yes
 No
 Unknown

Anti-TNF used since last assessment (from original REDCap project)?

Yes
 No
 Unknown

Anti-TNF used currently (from original REDCap project)?

Yes
 No
 Unknown

Infliximab used since last assessment?

Yes
 No
 Unknown

Infliximab used currently?

Yes
 No
 Unknown

Date started:

(MM/YYYY)

Date stopped:

(MM-YYYY)

Most recent dose and schedule:

Induction 5 mg/kg IV at 0, 2, and 6 weeks
 5 mg/kg IV every 4 weeks
 5 mg/kg IV every 6 weeks
 5 mg/kg IV every 8 weeks
 7.5 mg/kg IV every 4 weeks
 7.5 mg/kg IV every 6 weeks
 7.5 mg/kg IV every 8 weeks
 10 mg/kg IV every 4 weeks
 10 mg/kg IV every 6 weeks
 10 mg/kg IV every 8 weeks
 Other dose and schedule

Describe other dose and schedule:

Adalimumab used since last assessment?

Yes
 No
 Unknown

Adalimumab used currently?

- Yes
 No
 Unknown
-

Date started:

(MM/YYYY)

Date stopped:

(MM-YYYY)

Most recent dose and schedule:

- *Induction* 160 mg sc at week 0, 80 mg at week 2
 40 mg sc every 1 week
 40 mg sc every 2 weeks
 80 mg sc every 2 weeks
 Other dose and schedule
-

Describe other dose and schedule:

Certolizumab used since last assessment?

- Yes
 No
 Unknown
-

Certolizumab used currently?

- Yes
 No
 Unknown
-

Date started:

(MM/YYYY)

Date stopped:

(MM-YYYY)

Most recent dose and schedule:

- *Induction* 400mg sc at weeks 0, 2, and 4
 200mg sc every 2 weeks
 400mg sc every 2 weeks
 400mg sc every 4 weeks
 Other dose and schedule
-

Describe other dose and schedule:

Vedolizumab used since last assessment?

- Yes
 No
 Unknown
-

Vedolizumab used currently?

- Yes
 No
 Unknown
-

Date started:

(MM/YYYY)

Date stopped:

(MM/YYYY)

Most recent dose and schedule:

- *Induction* 300mg IV at 0, 2, and 6 weeks
- 300mg IV every 4 weeks
- 300mg IV every 6 weeks
- 300mg IV every 8 weeks
- Other dose and schedule

Describe other dose and schedule:

Ustekinumab used since last assessment?

- Yes
- No
- Unknown

Ustekinumab used currently?

- Yes
- No
- Unknown

Date started:

(MM/YYYY)

Date stopped:

(MM/YYYY)

Most recent dose and schedule:

- *Induction* weight-based IV dose at week 0
- 90mg sc every 4 weeks
- 90mg sc every 6 weeks
- 90mg sc every 8 weeks
- Other dose and schedule

Describe other dose and schedule:

NSAIDS used since last assessment?

- Yes
- No
- Unknown

NSAIDS used currently?

- Yes
- No
- Unknown

Most recent schedule:

- Daily
- Weekly
- Monthly
- Less than once per month

Probiotics used since last assessment?

- Yes
- No
- Unknown

Probiotics used currently? Yes
 No
 Unknown

Other biological therapies used since last assessment? Yes
 No
 Unknown

Other biological therapies used currently? Yes
 No
 Unknown

Specify type of other biological therapy:

Current Smoking Status

Has patient smoked since last assessment date ([prev_assess_date]): Yes
 No
 Unknown

Did patient start smoking since last assessment date ([prev_assess_date])? Yes
 No
 Unknown

Did patient stop smoking since last assessment date ([prev_assess_date])? Yes
 No
 Unknown

When did patient start smoking?

 (MM/YYYY)

When did patient stop smoking?

 (MM/YYYY)

Average number of cigarettes per day since last assessment ([prev_assess_date]) during period when patient was smoking:

 ((1 pack = 20 cigarettes))

Please check this box if the number of cigarettes per day is unknown: Unknown

Current Smoking Status (from original REDCap project)

Smoking status: Current smoker
 Ex-smoker
 Non-smoker
 Unknown

Year started smoking:

 (YYYY)

Year stopped smoking:

(YYYY)

No. of cigarettes per day:

((1 pack = 20 cigarettes))

Please check this box if the number of cigarettes per day is unknown:

Unknown

Height (complete only if patient is under 18)

Height:

Height unit:

inches
 centimeters

If height is unknown, please check this box:

Height unknown

Weight

Weight:

Weight unit:

pounds
 kg

If weight is unknown, please check this box:

Weight unknown

Stool Collection

Check here to indicate that stool was not obtained at this timepoint:

Stool Not Obtained

Stool collection is a REQUIRED component of the study protocol. If stool was not obtained at this timepoint, please provide explanation.

Date of stool collection:

Time stool collected:

Have you taken antibiotics in the last month?

Yes
 No

If "Have you taken antibiotics in the last month?" is not answered, please check this box:

Not Answered

Name of antibiotic:

Dose:

Are you currently taking antibiotics?

Yes
 No

On what date did you stop?

For office use

Date received:

Collection container barcode ID:

5ml aliquot ID 1:

5ml aliquot ID 2:

5ml aliquot ID 3:

Yearly Status Check

Complete this form using your local medical records and/or by contacting the patient directly.

If patient has had a colonoscopy since index resectional surgery or last yearly status check, complete the corresponding Endoscopy Form(s).

Note that this form should be completed at 1, 2, 3, 4, and 5 years from the date of index resectional surgery ([recruitment_arm_1][index_date]).

Click "Today" to enter today's date:

(Enter today's date)

Has patient had colonoscopy since ileal resection surgery or last yearly status check (whichever is more recent)?

- Yes
 No
 Unknown

Check here if unable to contact patient

Unable to contact patient

Reason for unknown:

Status Confirmation

Important note: All endoscopies that occur during the five-year post-surgical study period must be entered in REDCap, even if the endoscopy occurred off-site or samples were not obtained. Do not check the box below until you can confirm that all endoscopies that have occurred to date have been captured.

If the participant has withdrawn from or has completed the study, be sure to also complete a Withdrawal or Study Completion form.

Click "Today" to enter today's date

(MM-DD-YYYY)

Participant has been contacted and/or clinical record has been reviewed AND all endoscopies have been entered in REDCap.

Confirmed

Withdrawal

Reminder: Complete a final Status Confirmation form on or after the withdrawal date indicated below.

Date of withdrawal:

Reason for withdrawal:

- First endoscopy performed off-site
- No samples obtained at first endoscopy
- Patient moved
- Patient will not return to GRC (explain below)
- Patient no longer wishes to participate
- Physician withdrew patient from study
- Patient determined to be ineligible (describe below)
- Other (describe below)

Explain why patient will not return to GRC:

Describe why patient is ineligible:

Describe other reason for withdrawal:

Has patient had colonoscopy since index resectional surgery or last yearly status check (whichever is more recent)?

- Yes
- No
- Unknown

Migrated from old study: Patient had first endoscopy before withdrawal date

- Migrated from old study: Patient had first endoscopy before withdrawal date

Please check here if patient requested that data and/or samples be destroyed:

- Destroy samples
- Destroy data

Study Completion

Reminder: Complete a final Status Confirmation form on or after the study completion date indicated below.

If patient has been withdrawn from the study, do not complete this form; instead, complete a Withdrawal Form.

Study completion date: _____

Indicate reason for study completion:

- Three post-surgical endoscopies with samples have been completed
- Five years have elapsed since index resectional surgery
- Patient completed study under original 24-month protocol
- Patient aged out of pediatric care to adult care at a different institution

Redaction Confirmation

Redaction verified: Operative report Redaction verified

Redaction verified: Surgical pathology report Redaction verified

Redaction verified: Recruitment CBC report Redaction verified

Redaction verified: Imaging 1 report Redaction verified

Redaction verified: Imaging 2 report Redaction verified

Redaction verified: Imaging 3 report Redaction verified

Redaction verified: Endoscopy report Redaction verified

Redaction verified: Endoscopic pathology report Redaction verified