Gender: M F

Additional Lab Results Form

ID NUMBER: | | | | | | | |

FORM CODE: ALF
VERSION: A 10/8/13

Contact Occasion | | |

Seq # | | |

ALF0a Date of Form Completion: | | / | | / | | | | |

ALF0b Staff Code: | | | |

ALF0c FDF # | | |

Instruction: Contact Occasion above is to be coded with CO# associated with the blood draw.

1. Immunomodulator Monitoring: ❑ Yes ❑ No → Q6 ALF1

   a. Date of Blood Draw (dd / mmm /yyyy) ____ ____ /____ ____ ____/ ____ ____ ____ ____ ALF1a

   b. Lab Used _____ ALF1b

		A. Performed Y	A. Performed N	B. Units Conventional (1)	B. Units Other (2)	C. Result
ALF2a	2. TPMT Activity	❑	❑ → Q3	❑ *Level* ALF2b	❑ _____ ALF2b1	_____ ALF2c
ALF3a	3. 6-TG	❑	❑ → Q4	❑ *pmol/8 x 10^8 RBCs* ALF3b	❑ _____ ALF3b1	_____ ALF3c
ALF4a	4. 6-MMP	❑	❑ → Q5	❑ *pmol/8 x 10^8 RBCs* ALF4b	❑ _____ ALF4b1	_____ ALF4c
ALF5a	5. TPMT Genotype	❑	❑ → Q6			

   a. Genotype Result (select one): ALF5b
   ❑ TPMT*1/TPMT*1 (normal)
   ❑ TPMT*1/TPMT*3 (intermediate)
   ❑ TPMT*3/TPMT*3 (low to absent)

6. Calcineurin Inhibitor Monitoring: ❑ Yes ❑ No → Q8 ALF6

   a. Date of Blood Draw (dd / mmm /yyyy) ____ ____ /____ ____ ____/ ____ ____ ____ ____ ALF6a

   b. Lab Used _____ ALF6b ALF6b1_Other lab used

		A. Performed Y	A. Performed N	B. Units Conventional (1)	B. Units Other (2)	C. Result
ALF7a	7. Cyclosporin Level	❑	❑ → Q8	❑ *ng/ml* ALF7b	❑ ALF7b1 _____	ALF7c _____
ALF8a	8. Tacrolimus Level	❑	❑ → Q9	❑ *microg/L* ALF8b	❑ ALF8b1 _____	ALF8c _____

9. Biologic Therapy Monitoring: ❑ Yes ❑ No → END ALF9

   a. Date of Blood Draw (dd / mmm /yyyy) ____ ____ /____ ____ ____/ ____ ____ ____ ____ ALF9a

   b. Lab Used _____ ALF9b ALFb1 Other lab used

		A. Performed Y	A. Performed N	B. Units Conventional (1)	B. Units Other (2)	C. Result
ALF10a	10. Infliximab Level	❑	❑ → Q11	❑ *microg/mL* ALF10b	❑ ALF10b1 _____	ALF10c _____
ALF11a	11. ATI	❑	❑ → END	❑ *microg/mL* ALF11b	❑ ALF11b _____	ALF11c _____

Gender: M F

Additional Medical Therapy Form

ID NUMBER: | | | | | | | |

FORM CODE: AMT
VERSION: A 06/18/12

Contact Occasion | |

Seq # | |

Date of Form Completion: | | / | | | | / | | AMT0a | |

Staff Code: | | AMT0b | |

FDF # | | AMT0c

A. Specific Agent for Additional Medical Therapy

1. Agent Name: AMT1

❑ (1) Azathioprine ❑ (2) 6-MP ❑ (3) Methotrexate SC ❑ (4) Methotrexate Oral
❑ (5) Tacrolimus ❑ (6) Cyclosporine ❑ (7) Infliximab ❑ (8) Adalimumab
❑ (9) Other: _____

B. Summary of Indication for Additional Medical Therapy

2. Was this therapy instituted since last review? ..... ❑ Yes ❑ No→Q5 AMT2
3. a. Date commenced: (dd/mmm/yyyy) __ __ / __ __ __ / AMT3a __ __ __ __ b. Dose (mg): AMT3b _____ c. Freq: AMT3c _____
4. Please complete the following criteria for instituting additional medical therapy since last review.

Criteria	Yes	No
a. The PUCAI continues to be ≥34 despite a minimum of 2-4 weeks of ≥1mg/kg/day corticosteroid	❑	❑ AMT4a
b. Failure to wean prednisone below 0.5 mg/kg/day by week 6	❑	❑ AMT4b
c. Continued activity (PUCAI >10) and need for CS at week 12-24	❑	❑ AMT4c
d. Clinical relapse within 6 months of initial successful weaning of prednisone	❑	❑ AMT4d
e. Adverse reaction to mesalamine	❑	❑ AMT4e
f. Hospitalized participant with severe colitis (PUCAI ≥65) and failure to respond to intravenous CS within 7 days	❑	❑ AMT4f
g. The Participant has been hospitalized subsequent to first attempted induction course	❑	❑ AMT4g
h. At the discretion of the attending physician.	❑	❑ AMT4h
i. As a combination and/or bridging therapy with a biologic agent	❑	❑ AMT4i

B. Reminders about initiation of Additional Medical Therapy

- TPMT activity should be measured prior to the initiation of Thiopurine Therapy
- Metabolites measurement is at the discretion of the physician
- Participants should have regular monitoring of CBC and serum chemistries
- Participants will be considered treatment failures with respect to the study's primary outcome.
- Participants will continue to be followed in the study

C. Additional Medical Therapy Reduced/Increased

5. Was dose of this therapy altered since last review?..... ❑ Yes ❑ No→Q8 AMT5
6. a. Date altered: (dd/mmm/yyyy): __ __ / __ __ __ / AMT6a __ __ __ __ b. Dose (mg): AMT6b _____ c. Freq: AMT6c _____
7. Reason this medication was altered:
   a. Poorly effective .....❑ Yes ❑ No AMT7a
   b. Suspected intolerance ....❑ Yes ❑ No AMT7b
   c. Suspected drug toxicity .❑ Yes ❑ No AMT7c
   d. Participant's choice.....❑ Yes ❑ No AMT7d
   e. Other .....❑ Yes ❑ No AMT7e
      1. Specify: AMT7e1 _____

D. Additional Medical Therapy Ceased

8. Was dose of additional medical therapy stopped since last review?..... ❑ Yes ❑ No→End AMT8
9. Date this therapy was stopped: (dd/mmm/yyyy): __ __ / __ __ __ / __ __ __ __ AMT9
10. Reason this medication was stopped:
    a. Ineffective.....❑ Yes ❑ No AMT10a
    b. Suspected intolerance ....❑ Yes ❑ No AMT10b
    c. Suspected drug toxicity .❑ Yes ❑ No AMT10c
    d. Participant's choice.....❑ Yes ❑ No AMT10d
    e. Other .....❑ Yes ❑ No AMT10e
       1. Specify: AMT10e1 _____

Gender: M F

Additional Medical Therapy Form

ID NUMBER: | | | | | | | |

FORM CODE: AMT
VERSION: B 12/16/13

Contact Occasion | |

Seq # | |

Date of Form Completion: | | / | | | / | | AMT0a | |

Staff Code: AMT0b | |

FDF # AMT0c

A. Specific Agent for Additional Medical Therapy

1. Agent Name: AMT1
   - ❑ (1) Azathioprine
   - ❑ (2) 6-MP
   - ❑ (3) Methotrexate SC
   - ❑ (4) Methotrexate Oral
   - ❑ (5) Tacrolimus
   - ❑ (6) Cyclosporine
   - ❑ (7) Infliximab
   - ❑ (8) Adalimumab
   - ❑ (9) Other: _____

B. Summary of Indication for Additional Medical Therapy

2. Was this therapy instituted since last review? ..... ❑ Yes ❑ No→Q5 AMT2
3. a. Date commenced: (dd/mmm/yyyy) __ __ / __ __ __ / __ __ __ __ AMT3a b. Dose (mg): AMT3b c. Freq: AMT3c
4. Please complete the following criteria for instituting additional medical therapy since last review.

Criteria	Yes	No
a. The PUCAI continues to be ≥34 despite a minimum of 2-4 weeks of ≥1mg/kg/day corticosteroid	❑	❑ AMT4a
b. Failure to wean prednisone below 0.5 mg/kg/day by week 6	❑	❑ AMT4b
c. Continued activity (PUCAI >10) and need for CS at week 12-24	❑	❑ AMT4c
d. Clinical relapse within 6 months of initial successful weaning of prednisone	❑	❑ AMT4d
e. Adverse reaction to mesalamine	❑	❑ AMT4e
f. Hospitalized participant with severe colitis (PUCAI ≥65) and failure to respond to intravenous CS within 7 days	❑	❑ AMT4f
g. The Participant has been hospitalized subsequent to first attempted induction course	❑	❑ AMT4g
h. At the discretion of the attending physician.	❑	❑ AMT4h
i. As a combination and/or bridging therapy with a biologic agent	❑	❑ AMF4i
j. Non-luminal IBD indication (e.g., arthritis, liver disease and other) Specify: _____ AMT4j1	❑	❑ AMT4j

B. Reminders about initiation of Additional Medical Therapy

- TPMT activity should be measured prior to the initiation of Thiopurine Therapy
- Metabolites measurement is at the discretion of the physician
- Participants should have regular monitoring of CBC and serum chemistries
- Participants will be considered treatment failures with respect to the study's primary outcome.
- Participants will continue to be followed in the study

C. Additional Medical Therapy Reduced/Increased

5. Was dose of this therapy altered since last review? ..... ❑ Yes ❑ No→Q8 AMT5
6. a. Date altered: (dd/mmm/yyyy): __ __ / __ __ __ / __ __ __ __ AMT6a b. Dose (mg): AMT6b c. Freq: AMT6c
7. Reason this medication was altered:
   - a. Poorly effective .....❑ Yes ❑ No AMT7a
   - b. Suspected intolerance ....❑ Yes ❑ No AMT7b
   - c. Suspected drug toxicity .❑ Yes ❑ No AMT7c
   - d. Participant's choice.....❑ Yes ❑ No AMT7d
   - e. Other .....❑ Yes ❑ No AMT7e
     1. Specify: _____ AMT7e1

D. Additional Medical Therapy Ceased

8. Was dose of additional medical therapy stopped since last review? ..... ❑ Yes ❑ No→End AMT8
9. Date this therapy was stopped: (dd/mmm/yyyy): __ __ / __ __ __ / __ __ __ __ AMT9
10. Reason this medication was stopped:
    - a. Ineffective.....❑ Yes ❑ No AMT10a
    - b. Suspected intolerance ....❑ Yes ❑ No AMT10b
    - c. Suspected drug toxicity .❑ Yes ❑ No AMT10c
    - d. Participant's choice.....❑ Yes ❑ No AMT10d
    - e. Other .....❑ Yes ❑ No AMT10e
      1. Specify: _____ AMT10e1

Gender: M F

Additional Medical Therapy Form

ID NUMBER: | | | | | | | |

FORM CODE: AMT
VERSION: C 01/07/2015

Contact Occasion | |

Seq # | |

Date of Form Completion: AMT0a / / /

Staff Code: AMT0b

FDF # AMT0c

A. Specific Agent for Additional Medical Therapy

1. Agent Name: ❑ (1) Azathioprine ❑ (2) 6-MP ❑ (3) Methotrexate SC ❑ (4) Methotrexate Oral AMT1a
❑ (5) Tacrolimus ❑ (6) Cyclosporine ❑ (7) Infliximab ❑ (8) Adalimumab
❑ (9) Other: _____ ❑ (10) Other 5-ASA after week 52:_____

B. Summary of Indication for Additional Medical Therapy

2. Was this therapy instituted since last review? ..... ❑ Yes ❑ No→Q5 AMT2
3. a. Date commenced: (dd/mmm/yyyy) __ __ AMT3a __ __ / __ __ __ __ b. Dose (mg): _____ AMT3b c. Freq: _____ AMT3c
4. Please complete the following criteria for instituting additional medical therapy since last review.

	Criteria	Yes	No
AMT4a	a. The PUCAI continues to be ≥34 despite a minimum of 2-4 weeks of ≥1mg/kg/day corticosteroid	❑	❑
AMT4b	b. Failure to wean prednisone below 0.5 mg/kg/day by week 6	❑	❑
AMT4c	c. Continued activity (PUCAI >10) and need for CS at week 12-24	❑	❑
AMT4d	d. Clinical relapse within 6 months of initial successful weaning of prednisone	❑	❑
AMT4e	e. Adverse reaction to mesalamine	❑	❑
AMT4f	f. Hospitalized participant with severe colitis (PUCAI ≥65) and failure to respond to intravenous CS within 14 days	❑	❑
AMT4g	g. The Participant has been hospitalized subsequent to first attempted induction course	❑	❑
AMT4h	h. At the discretion of the attending physician.	❑	❑
AMT4i	i. As a combination and/or bridging therapy with a biologic agent	❑	❑
AMT4j	j. Non-luminal IBD indication (e.g., arthritis, liver disease and other) Specify: AT4j1 _____	❑	❑

B. Reminders about initiation of Additional Medical Therapy

- TPMT activity should be measured prior to the initiation of Thiopurine Therapy
- Metabolites measurement is at the discretion of the physician
- Participants should have regular monitoring of CBC and serum chemistries
- Participants will be considered treatment failures with respect to the study's primary outcome.
- Participants will continue to be followed in the study

C. Additional Medical Therapy Reduced/Increased

AMT5 5. Was dose of this therapy altered since last review? ..... ❑ Yes ❑ No→Q8

6. a. Date altered: (dd/mmm/yyyy): __ __ / AMT6a / __ __ __ __ b. Dose (mg): _____ AMT6b c. Freq: _____ AMT6c

7. Reason this medication was altered:

AMT7a a. Poorly effective ..... ❑ Yes ❑ No
AMT7b b. Suspected intolerance .... ❑ Yes ❑ No
AMT7c c. Suspected drug toxicity . ❑ Yes ❑ No
d. Participant's choice..... ❑ Yes ❑ No AMT7d
e. Other ..... ❑ Yes ❑ No AMT7e
1. Specify: _____ AMT7f

D. Additional Medical Therapy Ceased

AMT8 8. Was dose of additional medical therapy stopped since last review? ..... ❑ Yes ❑ No→End

AMT9 9. Date this therapy was stopped: (dd/mmm/yyyy): __ __ / __ __ __ / __ __ __ __

10. Reason this medication was stopped:

AMT10a a. Ineffective..... ❑ Yes ❑ No
AMT10b b. Suspected intolerance .... ❑ Yes ❑ No
AMT10c c. Suspected drug toxicity . ❑ Yes ❑ No
d. Participant's choice..... ❑ Yes ❑ No AMT10
e. Other ..... ❑ Yes ❑ No AMT10e
1. Specify: _____ AMT10e1

Gender: M F

Ancillary Treatment Day Zero Form

ID NUMBER: | | | | | | | |

FORM CODE: ATZ
VERSION: A 05/25/12

Contact Occasion | |

SEQ # ATZ0c

Date of Form Completion: | | / ATZ0a | | / | | | | |

Staff Code: ATZ0b | | |

Category	Name	a. Received within 4 wks before Day 0		b. If received, approximate timing of first dose:		
		Yes	No	> 4wks Before Day (0) (1)		Within 4 wks Day (0) (2)
A. Daily Supplements						
1. Probiotic Supplement	ATZ1a	❑	❑→ Q2	❑	ATZ1b	❑
2. Omega-3 Supplement	ATZ2a	❑	❑→ Q3	❑	ATZ2b	❑
B. Antibiotics						
3. Metronidazole (Flagyl)	ATZ3a	❑	❑→ Q4	❑	ATZ3b	❑
4. Ciprofloxacin	ATZ4a	❑	❑→ Q5	❑	ATZ4b	❑
5. Rifaxamin (Xifaxin)	ATZ5a	❑	❑→ Q6	❑	ATZ5b	❑
6. Vancomycin	ATZ6a	❑	❑→ Q7	❑	ATZ6b	❑
7. Other, please specify: _____	ATZ7a	❑	❑→ Q8	❑	ATZ7b	❑
C. Other Medications						
8. Anti-diarrheal Agents(eg: Loperamide, Diphenoxylate HCl, etc)	ATZ8a	❑	❑→ Q9	❑	ATZ8b	❑
9. Contraceptive (Oral, Injectable, Transdermal)	ATZ9a	❑	❑→ Q10	❑	ATZ9b	❑
10. NSAIDs	ATZ10a	❑	❑→ Q11	❑	ATZ10b	❑
D. Specific Medications						
11. Oral Vitamin D	ATZ11a	❑	❑→ End	❑	ATZ11b	❑

11c. **If taking** Oral Vitamin D, what is the total dose? __ __ __ __ __ IU ATZ11c

11d. Dose frequency: ❑ Daily ❑ Weekly ATZ11d

PROTECT

Gender: M F

Ancillary Treatment Follow-up Form

ID NUMBER: | | | | | | | |

FORM CODE: ATF
VERSION: A 06/18/12

Contact Occasion | |

Seq # | |

Date of Form Completion: | | / ATF0a | | / | | | | |

Staff Code: ATF0b | |

FDF # ATF0c | |

Category	Name	A. Active therapy at last review? Yes	No	B. Commenced/ Ongoing since last review Yes	No	C. Start Date (if commenced) dd/mmm/yyyy	D. Stop Date (if stopped) dd/mmm/yyyy
Daily Supplements							
1.	Probiotic Supplement	ATF1a ❑	❑	ATF1b ❑	❑	_ _/ATF1c_ _ _ _	_ _/ATF1d_ _ _ _
2.	Omega-3 Supplement	ATF2a ❑	❑	ATF2b ❑	❑	_ _/ATF2c_ _ _ _	_ _/ATF2d_ _ _ _
Antibiotics							
3.	Metronidazole (Flagyl)	ATF3a ❑	❑	ATF3b ❑	❑	_ _/ATF3c_ _ _ _	_ _/ATF3d_ _ _ _
4.	Ciprofloxacin	ATF4a ❑	❑	ATF4b ❑	❑	_ _/ATF4c_ _ _ _	_ _/ATF4d_ _ _ _
5.	Rifaxamin (Xifaxin)	ATF5a ❑	❑	ATF5b ❑	❑	_ _/ATF5c_ _ _ _	_ _/ATF5d_ _ _ _
6.	Vancomycin	ATF6a ❑	❑	ATF6b ❑	❑	_ _/ATF6c_ _ _ _	_ _/ATF6d_ _ _ _
7.	Other, please specify: _____	ATF7a ❑	❑	ATF7b ❑	❑	_ _/ATF7c_ _ _ _	_ _/ATF7d_ _ _ _
Other Medications							
8.	Anti-diarrheal Agents (eg: Loperamide, Diphenoxylate HCl, etc)	ATF8a ❑	❑	ATF8b ❑	❑	ATF8c _ _/_ _ _/_ _ _ _	ATF8d _ _/_ _ _/_ _ _ _
9.	Contraceptive (Oral, Injectable, Transdermal)	ATF9a ❑	❑	ATF9b ❑	❑	ATF9c _ _/_ _ _/_ _ _ _	ATF9d _ _/_ _ _/_ _ _ _
10.	NSAIDs	ATF10a ❑	❑	ATF10b ❑	❑	ATF10c _ _/_ _ _/_ _ _ _	ATF10d _ _/_ _ _/_ _ _ _
11.	Anticoagulant	ATF11a ❑	❑	ATF11b ❑	❑	ATF11c _ _/_ _ _/_ _ _ _	ATF11d _ _/_ _ _/_ _ _ _
Specific Medications							
12.	Oral Vitamin D	ATF12a ❑	❑	ATF12b ❑	❑	ATF12c _ _/_ _ _/_ _ _ _	ATF12d _ _/_ _ _/_ _ _ _

12e. If taking Oral Vitamin D, what is the total dose? ATF12e _ _ _ _ _ IU

12f. Dose frequency: ❑ Daily ❑ Weekly ATF12f

Gender: M F

Baseline Demographic Form

ID NUMBER: ☐☐☐☐☐☐☐ FORM CODE: BDF VERSION: A 04/12/2013 Contact Occasion ☐☐ SEQ # ☐☐

Date of Contact: ☐☐/☐☐/☐☐☐☐ BDF0a Staff Code: ☐☐☐ BDF0b

1. Age: ____ ____ year(s) ____ ____ month(s) BDF1

2. Gender: ❑ (1) **M**ale ❑ (2) **F**emale BDF2

		Yes	No	Unknown	Refused	
3.	Is your child of Hispanic ethnicity (origin)?	❑	❑	❑	❑	BDF3
4.	Which of the following best describes your child's race? *(Answer each.)*					
a.	White	❑	❑	❑	❑	BDF4a
b.	Black or African-American	❑	❑	❑	❑	BDF4b
c.	Asian	❑	❑	❑	❑	BDF4c
d.	Native Hawaiian or Other Pacific Islander	❑	❑	❑	❑	BDF4d
e.	American Indian or Alaska Native	❑	❑	❑	❑	BDF4e
f.	Other	❑	❑	❑	❑	BDF4f

1. If other, please specify: _____ BDF4f1

5. Participant's country of birth: _____ BDF5

a. Is participant currently in country of origin? ❑**Y**es → End ❑**N**o BDF5a

b. Estimated date of arrival in present country: ____ ____ /____ ____ ____/ ____ ____ ____ ____ BDF5b
dd mmm yyyy

Central Lab Specimen Receipt

Lab ID: ☐☐☐☐☐☐☐

FORM CODE: CSR
VERSION: A 05/10/12

Date of Specimen Receipt: ☐☐/CSR0a☐/☐☐☐☐

Staff Code: CSR0b

All fields below are entered into DMS by scanning barcodes on the labels.

	A. Participant ID (CRF)	B. Specimen ID (CRF)	C. Specimen ID (Specimen Container)
1.	CSR1a	CSR1b	CSR1c
2.	CSR2a	CSR2b	CSR2c
3.	CSR3a	CSR3b	CSR3c
4.	CSR4a	CSR4b	CSR4c
5.	CSR5a	CSR5b	CSR5c
6.	CSR6a	CSR6b	CSR6c
7.	CSR7a	CSR7b	CSR7c
8.	CSR8a	CSR8b	CSR8c
9.	CSR9a	CSR9b	CSR9c
10.	CSR10a	CSR10b	CSR10c
11.	CSR11a	CSR11b	CSR11c
12.	CSR12a	CSR12b	CSR12c
13.	CSR13a	CSR13b	CSR13c
14.	CSR14a	CSR14b	CSR14c
15.	CSR15a	CSR15b	CSR15c

Central Reviewer Biopsy Histology Score Form

Reading Ctr ID: ☐☐☐☐☐☐☐

FORM CODE: CBH
VERSION: A 12/11/12

Date of Review: ☐☐/☐☐☐/☐☐☐☐ CBH0a

1. Slide identifier: H I S ____ ____ ____ ____ ____ CBH1

2. Reviewer's Identifier: ____ ____ ____ CBH2

3. Overall Grading of Inflammation in Rectal Biopsy: CBH3

Description (select one option only	Grade
None	❑ (1)
Chronic only	❑ (2)
Mild acute – no abscesses	❑ (3)
Moderate acute – few abscesses (≤10% of crypts)	❑ (4)
Marked acute – many abscesses (>10% of crypts)	❑ (5)

4. Eosinophilic Inflammation in Rectal Biopsy

a. Peak count (number per high field) _____/hpf (size of hpf = 0.3 mm^2) CBH4a

b. Description (select one option only) CBH4b

	Grade
None (peak count ≤ 32/hpf)	❑ (1)
Mucosal eosinophilia (peak count >32/hpf) but without epithelial invasion (i.e. ≤2 eosinophils in surface epithelium, ≤9 eosinophils in crypt epithelium)	❑ (2)
Eosinophilic cryptitis (>9 intraepithelial eos/crypt)	❑ (3)
Moderate eosinophilic – few abscesses (≤10% of crypts)	❑ (4)
Marked eosinophilic – many abscesses (>10% of crypts)	❑ (5)

5. Architectural Changes in Rectal Biopsy:

		Present (1)	Absent (2)	Unevaluable
CBH5a	a. Ulcer/Erosion	❑	❑	❑
CBH5b	b. Crypt distortion/atrophy	❑	❑	
CBH5c	c. Surface villiform changes	❑	❑	❑
CBH5d	d. Basal plasmacytosis	❑	❑	❑
CBH5e	e. Basal lymphoid aggregates	❑	❑	❑
CBH5f	f. Paneth cell metaplasia	❑	❑	
CBH5g	g. Granuloma	❑	❑	

Clinical Data Day Zero Form

Gender: M F

ID NUMBER: | | | | | | | |

FORM CODE: CDZ
VERSION: A 06/26/12

Contact Occasion | |

SEQ# | |

Date of Contact: | | / | | | / | | | | CDZ0a

CDZ0b Staff Code: | | |

A. Participant Anthropometry at Day 0

CDZ1a 1. a. Height (cm): ___ ___ ___ . ___ b. Measured in Clinic? ❑Yes ❑No CDZ1b

CDZ2a 2. a. Weight (kg): ___ ___ ___ . ___ b. Measured in Clinic? ❑Yes ❑No CDZ2b

CDZ3 3. Date measurements were taken: (dd/mmm/yyyy) ____ ____ /____ ____ ____/ ____ ____ ____ ____

CDZ4 4. Tanner Stage: ❑ (1) Physician assessed ❑ (2) Self-reported ❑ (3) Not assessed →Q8

CDZ5 5. Breasts: ..... ❑ (1) I ❑ (2) II ❑ (3) III ❑ (4) IV ❑ (5) V ❑ (6) Not Applicable

CDZ6 6. Pubic Hair: ..... ❑ (1) I ❑ (2) II ❑ (3) III ❑ (4) IV ❑ (5) V

CDZ7 7. Genitalia: ..... ❑ (1) I ❑ (2) II ❑ (3) III ❑ (4) IV ❑ (5) V ❑ (6) Not Applicable

CDZ8 8. Is the Patient Post-Menarchal?..... ❑ (1) Yes ❑ (2) No ❑ (3) Unknown ❑ (4) Not Applicable

CDZ8a a. If yes, estimated Date of Menarche: (dd/mmm/yyyy) ___ ___ /___ ___ ___/ ___ ___ ___ ___

CDZ9 9. Was a urinalysis performed?.....❑Yes ❑No→Q13

CDZ10 10. Date of urinalysis: (dd/mmm/yyyy) ___ ___ /___ ___ ___/ ___ ___ ___ ___

CDZ11 11. Was there blood in the urine? ..... ❑ (1) None/Small ❑ (2) Moderate/greater

CDZ12 12. Was there protein in the urine? ..... ❑ (1) None/Small ❑ (2) Moderate/greater

B. Physician Assessment at Day 0

CDZ13 13. Physician Global Assessment of Disease Activity prior to commencement of therapy:

❑ (1) None ❑ (2) Mild ❑ (3) Moderate ❑ (4) Severe ❑ (5) Fulminant

None/Inactive
The patient has a normal number of stools for them without abdominal pain or bleeding. Care must be taken not to confuse irritable bowel like symptoms with those of ulcerative colitis, though we recognize that may at times be difficult.

Mild
The patient generally has looser stools than normal and perhaps slightly more per day than normal. There is daily to occasional blood in the stool though the amount of blood is small. Cramping is mild or absent and in general the patient's activity is normal. There are no nocturnal symptoms.

Moderate
The patient is clearly having activity of the ulcerative colitis. Most of the stools or all of the stools are loose, the number is increased to 4 or more per day, blood is present in the majority of stools and amounts are increasing. Abdominal pain is variable. There may be some nocturnal symptoms. A patient's activity level may now be affected.

Severe
The patient is having 6 or more grossly bloody stools per day and nocturnal symptoms are noted each day. Abdominal pain is variable. The patient is generally unable to perform normal daily activity.

Fulminant
This patient is having **severe** symptoms and in addition has at least 2 of the following: fever of 38 or greater, tachycardia, hemoglobin <10 g/dl, abdominal cramping with abdominal tenderness. Patients with fulminant disease are hospitalized.

Note: Regarding the number of stools, care must be taken to not confuse urgency and tenesmus leading to incomplete evacuation with several stools occurring over a short time and, on the other hand, discrete trips to the bathroom to defecate that are separated by periods of 30 minutes or more.

Gender: M F

Clinical Data Follow-up Form

ID NUMBER: | | | | | | | |

FORM CODE: CDF
VERSION: A 02/20/13

Contact Occasion | |

Seq # | | |

Date of Form Completion: | | / | | CDF0a / | | | | |

Staff Code: CDF0b | | |

FDF # CDF0c | | |

A. Findings suggestive of a change in diagnosis to Crohn's Disease

1. Clinical Findings:
   a. Presence of perianal fistula, atypically located fissures, or significant skin tags ..... ❑Y ❑N ❑U CDF1

CDF2 2. Has disease extent been reassessed since last clinic visit? ..... ❑Y→DED ❑N→Q6← ❑U

3. Since the last visit, has the participant undergone Endoscopy? ..... ❑Y ❑N→Q5← ❑U CDF3

CDF3a a. Was there segmental colitis (ie: macroscopic and microscopic skip lesions) ..... ❑Y ❑N ❑U

CDF3b b. Was there stenosis, cobblestoning or significant linear ulceration in the Terminal Ileum ... ❑Y ❑N ❑U

4. Since the last visit, has the participant had a mucosal biopsy? ..... ❑Y ❑N→Q5 ←❑U CDF4

CDF4a a. Was there absolute histologic rectal sparing..... ❑Y ❑N ❑U

CDF4b b. Were there epithelial granulomas not related to crypt rupture..... ❑Y ❑N ❑U

5. Since the last visit, has the participant undergone any Imaging Studies? ..... ❑Y ❑N→Q6← ❑U CDF5

CDF5a a. Was there evidence of stricture or fistula ..... ❑Y ❑N ❑U

CDF5b b. CT enterography study consistent with CD..... ❑Y ❑N ❑U ❑D/A

CDF5c c. MR enterography study consistent with CD..... ❑Y ❑N ❑U ❑D/A

CDF5d d. Capsule endoscopy study consistent with CD ..... ❑Y ❑N ❑U ❑D/A

6. **Current diagnostic Impression:**..... ❑ **UC** ❑ **CD** → SWF CDF6

NOTE: If the participant is considered to have CD, then they are excluded from the study and will no longer be followed.

B. Clinical Assessment during Follow-up

CDF7 7. Height (cm): (1) ___ ___ ___ . ___ 8. Weight (kg): (1) ___ ___ ___ .___ CDF8

CDF9 9. Tanner Stage: ❑ (1) Physician assessed ❑ (2) Self-reported ❑ (3) Not assessed → Q13

CDF10 10. Breasts: .....❑ (1) I ❑ (2) II ❑ (3) III ❑ (4) IV ❑ (5) V ❑ (6) Not Applicable

CDF11 11. Pubic Hair: .....❑ (1) I ❑ (2) II ❑ (3) III ❑ (4) IV ❑ (5) V

CDF12 12. Genitalia: .....❑ (1) I ❑ (2) II ❑ (3) III ❑ (4) IV ❑ (5) V ❑ (6) Not Applicable

CDF13 13. Is the participant Post-Menarchal? ❑ (1) Yes ❑ (2) No ❑ (3) Unknown ❑ (4) Not Applicable

CDF14 14. Was a urinalysis performed? ...❑Yes ❑No→Q17 14a. Urinalysis date: (dd/mmm/yyyy) ___ ___ /___ ___ ___/ ___ ___ ___ ___ CDF14a

CDF15 15. Was there blood in the urine?..... ❑ (1) None/Small ❑ (2) Moderate/greater

CDF16 16. Was there protein in the urine?..... ❑ (1) None/Small ❑ (2) Moderate/greater

CDF17 17. Was stool sent for microbial analysis? ....❑Yes ❑No→Q19 17a. Analysis date: (dd/mmm/yyyy) ___ ___ /___ ___ ___/ ___ ___ ___ ___ CDF17a

18. Were any of the following pathogens detected?

CDF18a a. Salmonella..... ❑Y ❑N ❑U

CDF18b b. Campylobacter ..... ❑Y ❑N ❑U

CDF18c c. Clostridium difficile ..... ❑Y ❑N ❑U

d. Shigella ..... ❑Y ❑N ❑U CDF18d

e. E. coli 0157:H7 ..... ❑Y ❑N ❑U CDF18e

f. Viral pathogen ..... ❑Y ❑N ❑U CDF18f

C. Physician Assessment (refer to QxQ for definitions/instructions for Q19 and Q20)

19. Physician Global Assessment of Disease Activity today: CDF19

❑ (1) Not Performed ❑ (2) Inactive ❑ (3) Mild ❑ (4) Moderate ❑ (5) Severe ❑ (6) Fulminant

20. Physician Global Assessment of Disease Activity since last review: CDF20

❑ (1) Not Performed ❑ (3) Mild ❑ (5) Chronically Severe ❑ (7) N/A (wk 4)

❑ (2) Quiescent ❑ (4) Moderate ❑ (6) Chronically Severe with Remission

PROTECT

Gender: M F

Colectomy Data Form

ID NUMBER: | | | | | | | |

FORM CODE: CLF
VERSION: A 06/18/12

Contact Occasion | |

Seq # | |

Date of Form Completion: | | / CLF0a | | / | | | | |

Staff Code: CLF0a | | |

FDF # CLF0a | |

A. Colectomy Details:

1. Date of Colectomy: (dd/mmm/yyyy) ___ ___ / ___ ___ ___ / ___ ___ ___ CLF1
2. Timing: ..... ❑ (1) Elective (Planned) ❑ (2) Non-Elective (Un-planned) CLF2
3. Steroid Status at time of Colectomy: CLF3
   - ❑ (1) Refractory (active disease despite optimization of corticosteroids)
   - ❑ (2) Responsive but Dependent (unable to wean corticosteroids without recurrence of active disease)
   - ❑ (3) Responsive, currently successfully tapering
   - ❑ (4) Previously Dependent (currently steroid free)
   - ❑ (5) Previously Responsive (currently steroid free)
   - ❑ (6) Steroid Naive

B. Procedure:

4. Indication(s) for Colectomy

CLF4a	a. Acute Severe Colitis	❑Y	❑N
CLF4b	b. Known Perforation	❑Y	❑N
CLF4c	c. Failed Medical Therapy	❑Y	❑N
CLF4d	d. Neoplasia	❑Y	❑N
CLF4e	e. Toxic Megacolon	❑Y	❑N
CLF4f	f. Patient Preference (with medically controlled disease)	❑Y	❑N
CLF4g	g. Other	❑Y	❑N

CLFg1 1. Please Specify:_____

CLF5 5. Procedural Approach: ..... ❑ (1) Lap-Assisted ❑ (2) Lap converted to Open ❑ (3) Open

CLF6 6. Initial Procedure:

❑ (1) Subtotal, Diverting ileostomy ❑ (2) Subtotal, Pouch Formation, Diverting ileostomy ❑ (3) Subtotal, IPAA

7. Early Post-operative Complications (</= 30 days post procedure)

CLF7a	a. Wound Infection	❑Y	❑N
CLF7b	b. Sepsis	❑Y	❑N
CLF7c	c. Pneumonia	❑Y	❑N
CLF7d	d. Abdominal Abscess	❑Y	❑N
CLF7e	e. Deep Venous Thrombosis	❑Y	❑N
CLF7f	f. Pulmonary Embolism	❑Y	❑N
CLF7g	g. Small bowel obstruction	❑Y	❑N
CLF7h	h. Anastomotic Leak	❑Y	❑N
CLF7i	i. Prolonged Ileus (>5 days)	❑Y	❑N
CLF7j	j. Re-admission < 30 days post-discharge	❑Y	❑N
CLF7k	k. Other infections	❑Y	❑N

1. Please Specify: CLF7k1 _____

l. Other CLF7l ..... ❑Y ❑N

1. Please Specify: CLF7l1 _____

8. Late Post-operative Complications (> 30 days post procedure)

CLF8a	a. Deep Venous Thrombosis	❑Y	❑N
CLF8b	b. Pulmonary Embolism	❑Y	❑N
CLF8c	c. Small Bowel Obstruction	❑Y	❑N
CLF8d	d. Anastomotic Leak	❑Y	❑N
CLF8e	e. Other	❑Y	❑N

1. Please Specify: CLF8e1 _____

9. Pathology of Colectomy Specimen: CLF9

❑ (1) Consistent with UC ❑ (2) Indeterminante ❑ (3) Consistent with Crohn's Disease

PROTECT

Gender: M F

Confirmation of Diagnosis Form

ID NUMBER: | | | | | | | |

FORM CODE: COD
VERSION: A 06/26/12

Contact Occasion | |

Seq # | |

Date of Form Completion: | | COD0a | | | / | | | | |

Staff Code: COD0b | | |

To meet the study's definition of UC and qualify for study entry and ongoing participation, the subject must:

A. Have features consistent with Ulcerative Colitis

1. Clinical history: COD1a COD1b COD1c
   a. Diarrhea: .....❑Y ❑N ❑U b. Abdominal Pain: .....❑Y ❑ N ❑ U c. Rectal bleeding: .....❑Y ❑N ❑U

	Yes	No	Unknown	
2. Endoscopic Findings				
a. Diffuse continuous mucosal inflammation involving the rectum and extending proximally	❑	❑	❑	COD2a
b. Inflammation extends beyond the rectosigmoid junction	❑	❑	❑	COD2b
3. Histologic Findings:				
a. Cryptitis or Crypt abscesses	❑	❑	❑	COD3a
b. Mucin depletion, crypt distortion, crypt branching, crypt atrophy or basal lymphocytosis	❑	❑	❑	COD3b

B. Have excluded the presence of an Enteric infection:

4. Has a stool sample been sent for microbial analysis? (required)	❑	❑	❑	COD4

5. Were any of the following pathogens detected?

a. Salmonella	❑Y	❑N	❑U	COD5a	d. Shigella	❑Y	❑N	❑U COD5d
b. Campylobacter	❑Y	❑N	❑U	COD5b	e. E. coli 0157:H7	❑Y	❑N	❑U COD5e
c. Clostridium difficile	❑Y	❑N	❑U	COD5c	f. Viral pathogen	❑Y	❑N	❑U COD5f

C. Does the Participant have any non-classic findings of Ulcerative Colitis?

	Yes	No	Unknown	
6. The following features do NOT exclude a diagnosis of Ulcerative Colitis, but should be recorded:				
a. Rectal inflammation less severe than more proximal colon (relative rectal sparing)	❑	❑	❑	COD6a
b. Macroscopic patchiness (macroscopically normal colonic mucosa between two inflamed areas)	❑	❑	❑	COD6b
c. Periappendiceal inflammation in a patient without pancolitis (cecal patch)	❑	❑	❑	COD6c
d. Backwash ileitis in the presence of pancolitis (ileal erythema without ulceration)	❑	❑	❑	COD6d
e. Non-specific macroscopic gastritis (without distinct aphthous lesions)	❑	❑	❑	COD6e
f. Microscopic gastritis without granuloma	❑	❑	❑	COD6f
g. Serological reactivity to anti-microbial antigens (ASCA, CBir, ompC)	❑	❑	❑	COD6g

D. Are there any features highly suggestive for Crohn's Disease:

	Yes	No	Unknown	
7. Clinical Findings:				
a. Presence of perianal fistula, atypically located fissures, or significant skin tags?	❑	❑	❑	COD7a
8. Endoscopic Findings:				
a. Segmental colitis (ie: macroscopic and microscopic skip lesions)?	❑	❑	❑	COD8a
b. Stenosis, cobblestoning or significant linear ulceration in the terminal ileum	❑	❑	❑	COD8h
9. Histologic Findings:				
a. Absolute histologic rectal sparing	❑	❑	❑	COD9a
b. Epithelial granulomas not related to crypt rupture	❑	❑	❑	COD9b

	Yes	No	Unknown	Doesn't Apply	
10. Imaging Findings:					
a. Evidence of stricture or fistula	❑	❑	❑		COD10a
b. Barium contrast study consistent with CD	❑	❑	❑	❑	COD10b
c. CT enterography study consistent with CD	❑	❑	❑	❑	COD10c
d. MR enterography study consistent with CD	❑	❑	❑	❑	COD10d
e. Capsule endosocopy study consistent with CD	❑	❑	❑	❑	COD10e

11. Does the patient meet the study definition of UC? ❑Yes ❑No COD11

PROTECT

Gender: M F

Disease Extent Data Form

ID NUMBER: | | | | | | | |

FORM CODE: DED
VERSION: A 06/18/12

Contact Occasion | |

Seq # | |

Date of Form Completion: | | / | | | / | | DED0a

Staff Code: | | DED0b

FDF # | | DED0c

A. Imaging Summary

1. Timing of this Assessment: ❑ (1) Baseline ❑ (2) Follow-up DED1

2. Approximate date of assessment: (dd/mmm/yyyy) ___ ___ / ___ ___ ___ / ___ ___ ___ ___ DED2

3. Please indicate if any of the investigations listed below were performed:

		N (1)	P (2)		N (1)	P (2)	
DED3a	a. Upper Endoscopy	❑	❑	f. Abdo Ultrasound	❑	❑	DED3f
DED03b	b. Lower Endoscopy (Colon)	❑	❑→EEF	g. Abdo MRI	❑	❑	DED3f
DED3c	c. Lower Endoscopy (TI)	❑	❑→EEF	h. Ba Enema	❑	❑	DED3h
DED3d	d. Capsule Endoscopy	❑	❑	i. Abdo CT	❑	❑	DED3i
DED3e	e. UGI Series/Follow-through	❑	❑	j. WBC Labeled Scan	❑	❑	DED3j

N= Not performed *P= Performed*

B. Summary of Known Disease Location following this assessment

4. Please indicate disease involvement at all listed locations (check one option only for each site)

	NL (1)	MA (2)	MI (3)	NA (4)	
a. Oral	❑	❑	❑	❑	DED4a
b. Esophagus	❑	❑	❑	❑	DED4b
c. Stomach	❑	❑	❑	❑	DED4c
d. Duodenum	❑	❑	❑	❑	DED4d
e. Jej/Prox Ileum	❑	❑	❑	❑	DED4e
f. Distal Il/TI	❑	❑	❑	❑	DED4f
g. Cecum	❑	❑	❑	❑	DED4g
h. Asc Colon	❑	❑	❑	❑	DED4h
i. Trans Colon	❑	❑	❑	❑	DED4i
j. Desc Colon	❑	❑	❑	❑	DED4j
k. Sigmoid	❑	❑	❑	❑	DED4k
l. Rectum	❑	❑	❑	❑	DED4l

NL= Normal *MA = Macroscopic disease c/w IBD* *MI = Microscopic Disease only* *NA = Not Assessed*

Gender: M F

Eligibility and Registration Form

ID NUMBER: ☐☐☐☐☐☐☐ FORM CODE: ERF VERSION: A 06/19/12 Contact Occasion ☐☐ SEQ # ☐☐

Date of Form Completion: ☐☐/☐☐☐/☐☐☐☐ ERF0a Staff Code: ERF0b ☐

A. Reminder of Eligibility Requirements for the PROTECT Study

		Yes	No
1.	Is the patient ≥ 4 years and ≤17 years of age, and do they weigh ≥15 kg?	❑	❑ERF1
2.	Does the patient have a new diagnosis of presumed ulcerative colitis extending beyond the rectosigmoid?	❑	❑ERF2
3.	Has stool culture excluded enteric infection?	❑	❑ERF3
4.	Will the patient be available for a minimum of 12 months follow-up?	❑	❑ERF4
5.	Is appropriate consent from parent/guardian and patient obtainable?	❑	❑ERF5
6.	Is the patient's Disease Activity PUCAI score ≥10	❑	❑ERF6
7.	Has there been NO therapy initiated to treat this newly diagnosed UC?	❑	❑ ERF7

Note: If all of the answers above are 'YES' then the patient is eligible to participate in the study.

B. Reminder of Exclusion Criteria for the PROTECT Study

		Yes	No
8.	Has patient used oral or IV corticosteroids for any non-GI indication in past 4 weeks?	❑	❑ ERF8
9.	Has the patient used any 5-aminosalicylate product in the past 4 weeks?	❑	❑ ERF9
10.	Has the patient used an Isotretinoin in the past four weeks?	❑	❑ ERF10
11.	Does the patient have a history of use of anti-TNF/thiopurine/methotrexate for other medical conditions?	❑	❑ ERF11
12.	Has the patient used any investigational drug in the past four weeks?	❑	❑ ERF12
13.	Does the patient have a poorly controlled medical condition such as diabetes, congestive heart failure, etc.	❑	❑ ERF13
14.	Is the patient pregnant?	❑	❑ ERF14
15.	Does the patient have a history or presence of any condition causing significant malabsorption or GI motility or history of small bowel resection?	❑	❑ ERF15
16.	Does the patient have chronic renal disease with creatinine >1.5 the ULN?	❑	❑ ERF16
17.	Does the patient have hepatic disease (AST or ALP > 3 times the upper limit of normal in the absence of concomitant liver disease associated with ulcerative colitis)?	❑	❑ ERF17
18.	Does the patient have a history of coexisting chronic illness or evidence of significant organic or psychiatric disease which, in the Investigator's opinion, would prevent participation in the study?	❑	❑ ERF18
19.	Does the patient have a history of allergy or hypersensitivity to salicylates, aminosalicylates, or any component of the Pentasa capsule?	❑	❑ ERF19

Note: If all of the answers above are 'NO' then the patient is eligible to participate in the study.

C. Final Disposition of the Patient for the PROTECT Study

20. Select One Option: ERF20

❑ (1) Ineligible

❑ (2) Eligible and Enrolled

❑ (3) Eligible and not enrolled (PI's decision)

❑ (4) Eligible and not enrolled (Subject's decision)

Gender: M F

Eligibility and Registration Form

ID NUMBER: ☐☐☐☐☐☐☐ FORM CODE: ERF VERSION:B 02/13/2013 Contact Occasion ☐☐ SEQ # ☐☐

Date of Form Completion: ☐☐/☐☐/☐☐☐☐ ERF0a Staff Code: ☐☐☐ ERF0b

A. Reminder of Eligibility Requirements for the PROTECT Study

		Yes	No	
1.	Does the patient weigh ≥ 15 kg and has the patient achieved their 4th birthday and not yet their 18th?	❑	❑	ERF1
2.	Does the patient have a new diagnosis of presumed ulcerative colitis extending beyond the rectosigmoid?	❑	❑	ERF2
3.	Has stool culture excluded active enteric infection?	❑	❑	ERF3
4.	Will the patient be available for a minimum of 12 months follow-up?	❑	❑	ERF4
5.	Is appropriate consent from parent/guardian and patient obtainable?	❑	❑	ERF5
6.	Is the patient's Disease Activity PUCAI score ≥10	❑	❑	ERF6
7.	Has there been NO therapy initiated to treat this newly diagnosed UC?	❑	❑	ERF7

Note: If all of the answers above are 'YES' then the patient is eligible to participate in the study.

B. Reminder of Exclusion Criteria for the PROTECT Study

		Yes	No	
8.	Has the patient used oral or IV corticosteroids for any non-GI indication in past 4 weeks?	❑	❑	ERF8
9.	Has the patient used any 5-aminosalicylate product in the past 4 weeks?	❑	❑	ERF9
10.	Has the patient used an Isotretinoin in the past four weeks?	❑	❑	ERF10
11.	Does the patient have a history of use of anti-TNF/thiopurine/methotrexate for other medical conditions within the past 6 months?	❑	❑	ERF11
12.	Has the patient used any investigational drug in the past four weeks?	❑	❑	ERF12
13.	Does the patient have a poorly controlled medical condition such as diabetes, congestive heart failure, etc.	❑	❑	ERF13
14.	Is the patient pregnant?	❑	❑	ERF14
15.	Does the patient have a history or presence of any condition causing significant malabsorption or GI motility or history of small bowel resection?	❑	❑	ERF15
16.	Does the patient have chronic renal disease with creatinine >1.5 the ULN?	❑	❑	ERF16
17.	Does the patient have hepatic disease (AST or ALP >3 times the upper limit of normal in the absence of concomitant liver disease associated with IBD following full evaluation)?	❑	❑	ERF17
18.	Does the patient have a history of coexisting chronic illness or evidence of significant organic or psychiatric disease which, in the Investigator's opinion, would prevent participation in the study?	❑	❑	ERF18
19.	Does the patient have a history of allergy or hypersensitivity to salicylates, aminosalicylates, or any component of the Pentasa capsule?	❑	❑	ERF19

Note: If all of the answers above are 'NO' then the patient is eligible to participate in the study.

C. Final Disposition of the Patient for the PROTECT Study

20. Select One Option: ERF20

- ❑ (1) Ineligible
- ❑ (2) Eligible and Enrolled
- ❑ (3) Eligible and not enrolled (PI's decision)
- ❑ (4) Eligible and not enrolled (Subject's decision)

Gender: M F

Endoscopic Evaluation Form

ID NUMBER: ☐☐☐☐☐☐☐ FORM CODE: EEF VERSION: A 02/15/2013 Contact Occasion ☐☐ Seq # ☐☐

Date of Form Completion: ☐☐/☐☐☐/☐☐☐☐ EEF0a Staff Code: ☐☐☐ EEF0b FDF # ☐☐

A. Endoscopic Assessment of Disease

1. How were these data collected?
   - ❑ (1) Proceduralist (Contemporaneous) *(preferred)*
   - ❑ (2) Proceduralist (Retrospective)
   - ❑ (3) Retrospective Chart Review EEF1
   - ❑ (4) Not Obtainable

2. Date of assessment: (dd/mmm/yyyy) ___ ___ / ___ ___ ___ / ___ ___ ___ ___ EEF2

B. Endoscopic Data:

	A. Assessed Yes	A. Assessed No	B. Photo Avail Yes	B. Photo Avail No	C. Up-loaded Yes	C. Up-loaded No	D. JPG File name (patient ID and date)**
3. Rectum	❑ EEF3a	❑→Q4A	❑ EEF3b	❑→Q4A	❑ EEF3c	❑→Q4A	EEF3d _____
4. Sigmoid	❑ EEF4a	❑→Q5A	❑ EEF4b	❑→Q5A	❑* EEF4c	❑→Q5A	EEF4d _____
5. Desc. Colon	❑	❑ EEF5a					
6. Trans. Colon	❑	❑ EEF6a					
7. Asc. Colon	❑	❑ EEF7a					
8. Cecum	❑	❑ EEF8a					
9. Ileum	❑	❑ EEF9a					

Upload a single image of the most affected area, either the Rectum or the Sigmoid. Please do not upload more than one image.

*** JPG file naming convention:** *ParticipantID_Assessment Date; Example PGA0106_12JUN2012*

C. Endoscopic Assessment of Disease Severity (Mayo): *select one*

10. Severity Score for the Recto-sigmoid Colon at Diagnosis (please reference photo guide): EEF10
    - ❑ (0) Grade 0: Normal or inactive disease
    - ❑ (1) Grade 1: Mild Disease (erythema, decreased vascular pattern, mild friability)
    - ❑ (2) Grade 2: Moderate disease (marked erythema, absent vascular pattern, friability, erosions)
    - ❑ (3) Grade 3: Severe disease (spontaneous bleeding, ulceration)

D. Additional Data Collection

11. Calculate and record the participant's PUCAI at the time of Colonoscopy..... ❑Yes ❑No →PUC EEF11
12. Record the participant's Biopsy Histology Score..... ❑Yes ❑No →SBH EEF12

E. Safety Reporting

13. Did the participant experience a serious adverse event with this procedure? ❑Yes→SAE ❑No ❑Unknown EEF13

Gender: M F

Enroll Day Zero Form

ID NUMBER: | | | | | | | |

FORM CODE: EDZ
VERSION: A 04/11/2013

Contact Occasion | | |

SEQ # | | |

Date of Contact: | | / | | EDZ0a / | | | | |

Staff Code: EDZ0b | | |

A. Study Registration Details:

1. Has the participant been consented: ..... ❑Yes→ ICT CO:01 ❑No → Consent prior to data collection EDZ1
2. Has the participant's eligibility been reviewed and recorded: ..... ❑Yes ❑No → ERF EDZ2
3. Has the participant's core demographic data been recorded: ..... ❑Yes ❑No → BDF CO:01 EDZ3
4. Have details regarding confirmation of diagnosis been recorded: ... ❑Yes ❑No → COD C0:01 EDZ4

B. Clinical and Historical Data Collection:

5. Has the participant's environmental and family history been recorded: ..... ❑Yes ❑No → EFH CO:01 EDZ5
6. Has the participant's medical history been recorded: ..... ❑Yes ❑No → MES CO:01 EDZ6
7. Initial Imaging and Histological Assessment:
   a. Have you recorded the participant's baseline imaging and findings: ..... ❑Yes ❑No → DED CO:01 EDZ7a
   b. Have you recorded the participant's colonoscopic findings:
      ❑ (1) Flex sig/colonoscopy was not performed ❑ (2) Findings Recorded ❑ (3) Findings not recorded → DED CO:01 EDZ7b
   c. Have you recorded the participant's histology findings:
      ❑ (1) Biopsy was not performed→ Q12 ❑ (2) Findings Recorded ❑ (3) Findings not recorded → SBHCO:01 EDZ7c
8. Initial Clinical Disease Activity Data:
   a. Have you calculated and recorded the participant's PUCAI at the time of endoscopy: ..... ❑Yes ❑No→ PUC EDZ8a
   b. Have you calculated and recorded the participant's PUCAI at Day 0: ..... ❑Yes ❑No→ PUC EDZ8b
   c. Have you recorded the participant's anthropometrics and disease activity (PGA) at Day 0: ..... ❑Yes ❑No→ CDZ EDZ8c
   d. Have you recorded the participant's standard laboratory results at the commencement of treatment:
      ❑ (1) No lab investigations performed ❑ (2) Results Recorded ❑ (3) Results not recorded → LLR EDZ8d

C. Study Sample Collection:

9. Has the participant had any study specific samples collected this encounter? ..... ❑Y→ SCF CO:01 ❑N EDZ9

D. Therapy Data Collection:

10. Have details summarizing the participant's baseline IBD therapy been recorded: ..... ❑Yes ❑No → STZ EDZ10
11. Have details summarizing the participant's other therapies been recorded: ..... ❑Yes ❑No → ATZ EDZ11

E. Study Disposition:

12. Outcome of this encounter (Select one option only) EDZ12
    ❑ (1) Discontinued from Study→ SFF ❑ (2) Ongoing review

F. Next Contact

13. Timeframe to next scheduled review? (1) ___ ___ Day(s) ❑ (2) Not Applicable EDZ13

NOTE: As you complete each triggered form, please make sure to change your response to the triggered question.

Gender: M F

Environmental and Family History Form

ID NUMBER: | | | | | | | |

FORM CODE: EFH
VERSION: A 10/11/13

Contact Occasion | |

SEQ# | |

Date of Contact: | | / | | EFH0a / | | | | |

Staff Code: EFH0b | | |

A. Family Ethnic Demographics

	A. Stated Racial Background (record as text, see QxQ)	B. Stated Jewish Background* N (1)	J (2)	NA (3)	JA (4)	U (5)	C. Stated Hispanic Background+ H (1)	NH (2)	U (3)
1. Maternal grandmother	EFH1a _____	❑	❑	EFH1b ❑	❑	❑	❑	❑	❑ EFH1c
2. Maternal grandfather	EFH2a _____	❑	❑	EFH2b ❑	❑	❑	❑	❑	❑ EFH2c
3. Paternal grandmother	EFH3a _____	❑	❑	EFH3b ❑	❑	❑	❑	❑	❑ EFH3c
4. Paternal grandfather	EFH4a _____	❑	❑	EFH4b ❑	❑	❑	❑	❑	❑ EFH4c

**N= not Jewish; J= Jewish (type uncertain); NA=Jewish non-Ashkenazi; JA= Jewish Ashkenazi: U=Jewish heritage status unknown*

+H= Hispanic; NH= Non-Hispanic: U=Hispanic heritage status is unknown

B. Participant Environmental History

5. Was the participant a current smoker around the time of Dx? ..... ❑Y ❑N ❑U EFH5

6. Did the participant live at home with a smoker anytime during the 6 month period prior to Dx? ..... ❑Y ❑N ❑U EFH6

7. Has the participant undergone an appendectomy? ..... ❑Y ❑N ❑U EFH7

   a. If yes, please specify approximate date of appendectomy ____ ____ /____ ____ ____ / ____ ____ ____ ____ EFH7a
   dd mmm yyyy

8. Did the participant receive Accutane (isotretinoin) anytime during the 6 month period prior to Dx? ..... ❑Y ❑N ❑U EFH8

C. Summary of Familial History of IBD

9. Do any of the participant's full siblings have a known history of IBD?

Full Siblings

	Yes (1)	No (2)	Unknown (3)	N/A *(No Full Siblings)* (4)
a. Ulcerative Colitis	❑	❑	❑	❑ EFH9a
b. Crohn's Disease	❑	❑	❑	❑ EFH9b
c. IBD-U	❑	❑	❑	❑ EFH9c
d. Confirmed IBD (unaware type)	❑	❑	❑	❑ EFH9d

10. Biological Mother:

❑ (1) Ulcerative Colitis ❑ (2) Crohn's Disease ❑ (3) IBD-U ❑ (4) IBD (Type Unk) ❑ (5) No Hx of IBD ❑ (6) Unknown EFH10

11. Biological Father:

❑ (1) Ulcerative Colitis ❑ (2) Crohn's Disease ❑ (3) IBD-U ❑ (4) IBD (Type Unk) ❑ (5) No Hx of IBD ❑ (6) Unknown EFH11

Gender: M F

Follow-up Data Form

ID NUMBER: | | | | | | | |

FORM CODE: FDF
VERSION: A 02/15/2013

Contact Occasion | | |

Seq # | | |

Date of Contact: | | / | | | | / | | | | FDF0a

Staff Code: | | | FDA0b

FDF # | | | FDF0c

A. Data Collection Details:

1. Encounter was:..... ❑ (1) Scheduled ❑ (2) Un-scheduled FDF1

2. Data collected from: ..... ❑ (1) Participant Encounter → CDF FDF2
   ❑ (2) Telephone Review + Chart Review→ CDF
   ❑ (3) Chart Review Only → CDF
   ❑ (4) Telephone Only Review
   ❑ (5) No data available for this review→ Q7

B. Data Collection Activities

3. Assessment of Current Disease:
   a. Since the last review has the participant been admitted to hospital? .....❑Yes→ SAE & HDF ❑No FDF3a
   b. Have you calculated and recorded the participant's PUCAI? .....❑Yes ❑No→ PUC FDF3b
   c. Utilized the SEF form to query for side effects and adverse events since the last review?.....❑Yes ❑No→ SEF FDF3c
   d. Has the participant experienced any SAEs since last review? .....❑Yes→ SAE ❑No ❑Unknown FDF3e
   e. Has the participant reported any new EIMs or Medical Diagnosis since the last review?.....❑Yes→ MEF ❑No FDF3e
   f. Did the participant undergo colectomy prior to the last review? .....❑Yes→ SAE & PCF ❑No FDF3f

4. Is the participant currently on the standard treatment paradigm? .....❑Yes ❑No→ Q5 FDF4
   a. Outcome of Pentasa Therapy at this encounter: FDF4a
      ❑ (1) Not currently prescribed
      ❑ (2) Started therapy
      ❑ (3) Stopped therapy
      ❑ (4) Continue dose unchanged
      ❑ (5) Continue dose reduced
      ❑ (6) Continue dose increased
   b. Outcome of Steroid Therapy at this encounter: FDF4b
      ❑ (1) Not currently prescribed
      ❑ (2) Started therapy
      ❑ (3) Stopped therapy
      ❑ (4) Continue dose unchanged
      ❑ (5) Continue dose reduced
      ❑ (6) Continue dose increased

5. Record of Medical Therapy:
   a. Completed SMF to record the status of all Steroid and 5-ASA therapy ? .....❑Yes ❑No ❑Doesn't Apply FDF5a
   b. Completed SLR to record the status of all IM and rescue therapies?.....❑Yes ❑No ❑Doesn't Apply FDF5b
   c. Completed ATF to record the status of all Ancillary therapies? .....❑Yes ❑No ❑Doesn't Apply FDF5c

6. Record of Sample Collection:
   a. Has the participant had any standard laboratory tests done recently? .....❑Yes→ LLR ❑No FDF6a
   b. Has the participant had any study specific samples collected this encounter? .....❑Yes→ SCF ❑No FDF6b

7. Outcome of this Encounter (Select one option only): FDF7
   ❑ (1) Confirmed "lost to follow-up"→ SWF
   ❑ (2) Admitted to hospital→ SAE & HDF
   ❑ (3) Discontinued from study→ SWF
   ❑ (4) For ongoing outpatient review

C. Next Contact

8. Timeframe to next Scheduled Review? (1) ___ ___ Week(s) ❑ (2) Doesn't Apply FDF8

NOTE: As you complete each triggered form, please make sure to change your response to the triggered question.

PROTECT

Gender: M F

Follow-up Data Form

ID NUMBER: _____ FORM CODE: FDF VERSION: B 12/14/2015 Contact Occasion _____ Seq # _____

Date of Contact: ___/___/___ FDF0a _____ Staff Code: FDF0b _____ FDF # FDF0c _____

A. Data Collection Details:

1. Encounter was:..... ❑ (1) Scheduled ❑ (2) Un-scheduled FDF1

2. Data collected from: ..... ❑ (1) Participant Encounter → CDF FDF2
   ❑ (2) Telephone Review + Chart Review→ CDF
   ❑ (3) Chart Review Only → CDF
   ❑ (4) Telephone Only Review
   ❑ (5) No data available for this review→ Q7

Note: After Week 52, side effects (SEF/SEG) are optional.

B. Data Collection Activities: (After Year 1, refer to Post Week 52 form packet for required forms.)

3. Assessment of Current Disease:
   a. Since the last review has the participant been admitted to hospital? .....❑Yes→ SAE & HDF ❑No FDF3a
   b. Have you calculated and recorded the participant's PUCAI? .....❑Yes ❑No→ PUC FDF3b
   c. Utilized the SEF form to query for side effects and adverse events since the last review?.....❑Yes ❑No→ SEF FDF3c
   d. Has the participant experienced any SAEs since last review? .....❑Yes→ SAE ❑No ❑Unknown FDF3d
   e. Has the participant reported any new EIMs or Medical Diagnosis since the last review?.....❑Yes→ MEF ❑No FDF3e
   f. Did the participant undergo colectomy prior to the last review? .....❑Yes→ SAE & PCF ❑No FDF3f

4. Is the participant currently on the standard treatment paradigm? .....❑Yes ❑No→ Q5 FDF4
   a. Outcome of Pentasa Therapy at this encounter: FDF4a
      ❑ (1) Not currently prescribed ❑ (4) Continue dose unchanged ❑ (7) Alternative 5-ASA after week 52
      ❑ (2) Started therapy ❑ (5) Continue dose reduced
      ❑ (3) Stopped therapy ❑ (6) Continue dose increased
   b. Outcome of Steroid Therapy at this encounter: FDF4b
      ❑ (1) Not currently prescribed ❑ (4) Continue dose unchanged
      ❑ (2) Started therapy ❑ (5) Continue dose reduced
      ❑ (3) Stopped therapy ❑ (6) Continue dose increased

5. Record of Medical Therapy:
   a. Completed SMF to record the status of all Steroid and 5-ASA therapy ? .....❑Yes ❑No ❑Doesn't Apply FDF5a
   b. Completed SLR to record the status of all IM and rescue therapies?.....❑Yes ❑No ❑Doesn't Apply FDF5b
   c. Completed ATF to record the status of all Ancillary therapies? .....❑Yes ❑No ❑Doesn't Apply FDF5c

6. Record of Sample Collection:
   a. Has the participant had any standard laboratory tests done recently? .....❑Yes→ LLR ❑No FDF6a
   b. Has the participant had any study specific samples collected this encounter? .....❑Yes→ SCF ❑No FDF6b

7. Outcome of this Encounter (Select one option only): FDF7
   ❑ (1) Confirmed "lost to follow-up"→ SWF ❑ (3) Discontinued/completed the study→ SWF
   ❑ (2) Admitted to hospital→ SAE & HDF ❑ (4) For ongoing outpatient review

C. Next Contact

8. Timeframe to next Scheduled Review? (1) ___ ___ Week(s) ❑ (2) Doesn't Apply FDF8

NOTE: As you complete each triggered form, please make sure to change your response to the triggered question.

Gender: M F

Hospitalization Data Form

ID NUMBER: ☐☐☐☐☐☐☐ FORM CODE: HDF VERSION: A 04/10/2013 Contact Occasion ☐☐ Seq # ☐☐

Date of Form Completion: ☐☐/HDF0a☐☐/☐☐☐☐ Staff Code: HDF0b ☐☐ FDF # HDF0c ☐☐

A. Hospitalization Details (Duration of Stay > 23 hours):

1. Date of Admission: (dd/mmm/yyyy) ___ ___ / ___ ___ ___ / ___ ___ ___ ___ HDF1

2. Was the admission related to the participant's IBD? ..... ❑Y ❑N→Q8 HDF2

3. Admission Type: ❑ (1) Elective (Planned) ❑ (2) Non-Elective (Un-planned) HDF3

Note: Regardless of the reason, all hospital admissions after the day of consent, or that arise as a complication of a procedure on the date of consent, are considered SAEs; notify the DCC and complete an SAE form as soon as the event is known.

B. Indications

4. Indication(s) for Admission

   a. Severe Disease at initial presentation: ..... ❑Y ❑N HDF4a

   b. Disease Worsening: ..... ❑Y ❑N HDF4b

   c. Disease Complication: ..... ❑Y ❑N HDF4c

   d. Treatment Complication: ..... ❑Y ❑N HDF4d

   e. Planned operative Procedure (Related to Ulcerative Colitis): ..... ❑Y ❑N HDF4e

   f. Non-operative Procedure: ..... ❑Y ❑N HDF4f

   g. Other: ..... ❑Y ❑N HDF4g

      1. If other please specify: HDF4g1 _____

C. Activity Details

5. Initial Clinical Disease Activity Data at admission:

HDF5a a. Have you calculated and recorded the participant's PUCAI at the time of admission: ..... ❑Y ❑N→PUC ❑N/A

HDF5b b. Admission Weight (kg): ___ ___ ___ . ___

6. Did the participant undergo Colectomy during this admission? ..... ❑Y→CLF ❑N HDF6

7. Clinical Disease Activity Data at discharge:

HDF7a a. Have you calculated and recorded the participant's PUCAI at the time of discharge: ..... ❑Y ❑N →PUC ❑N/A

HDF7b b. Discharge Weight (kg): ___ ___ ___ . ___

8. Date of Discharge: (dd/mmm/yyyy) ___ ___ / ___ ___ ___ / ___ ___ ___ ___ HDF8

Gender: M F

Informed Consent Tracking

ID NUMBER: | | | | | | | |

FORM CODE: ICT
VERSION: A 06/18/12

Contact Occasion | | |

Seq # | | |

Date of Form Completion: | | / | | | | / | | | | | ICT0a

Staff Code: | | ICT0b |

FDF # | | ICT0c

A. CONSENT STATUS

1. Date of consent or consent modification : ____ ____ /____ ____ ____/ ____ ____ ____ ____ ICT1
   dd mmm yyyy

2. Timing of consent/assent: ❑ (1) Initial study consent ICT2
   ❑ (2) Modification of consent →Q4

3. Was assent obtained: ..... ❑Yes ❑No ICT3

4. Consent signed or modified by *(select one)*: ICT4

   Subject ..... ❑ (1)
   Mother ..... ❑ (2)
   Father ..... ❑ (3)
   Both Parents..... ❑ (4)
   Legal Guardian ..... ❑ (5)
   Other ..... ❑ (6)

   a. If other, please specify:_____ ICT4a

5. Type of consent/assent *(select one)* ICT5

   Full ..... ❑ (1)→End
   Partial Consent ..... ❑ (2)
   Full Withdrawal ..... ❑ (3) →SWF

   a. If partial consent, please specify: _____ →End ICT5a

B. SPECIMEN CONSENT

Restrictions on consent of study specimen *(indicate all that apply):*

		A. Restrictions		B. If yes, please specify:	
6.	Use/storage of archived plasma ICT6a	❑Y	❑N	_____	ICT6b
7.	Use/storage of archived DNA ICT7a	❑Y	❑N	_____	ICT7b
8.	Use/storage of archived stool ICT8a	❑Y	❑N	_____	ICT8b
9.	Use/storage of archived rectal biopsies ICT9a	❑Y	❑N	_____	ICT9b
10.	Use/storage of archived colonoscopy images ICT10a	❑Y	❑N	_____	ICT10b

Gender: M F

Informed Consent Tracking

ID NUMBER: | | | | | | | |

FORM CODE: ICT
VERSION: B 02/07/2013

Contact Occasion | |

Seq # | |

Date of Form Completion: | | / ICT0a | | / | | | | |

Staff Code: ICT0b | |

FDF # ICT0c

A. CONSENT STATUS

1. Date of consent or consent modification : ____ ____ /____ ____ ____/ ____ ____ ____ ____ ICT1
   dd mmm yyyy

2. Timing of consent/assent: ❑ (1) Initial study consent ICT2
   ❑ (2) Modification of consent →Q4

3. Was assent obtained: ..... ❑Yes ❑No ICT3

4. Consent signed or modified by *(select one)*: ICT4

   Subject ..... ❑ (1)
   Mother ..... ❑ (2)
   Father ..... ❑ (3)
   Both Parents..... ❑ (4)
   Legal Guardian ..... ❑ (5)
   Other ..... ❑ (6)

   a. If other, please specify:_____ ICT4a

5. Type of consent/assent *(select one)* ICT5

   Full ..... …… ❑ (1)→End
   Partial Consent ..... …… ❑ (2)
   Full Withdrawal ..... …… ❑ (3)→SWF
   Expansion of consent (Week 52 substudy) ❑ (4) →End
   Expansion of consent (SOC biopsies during follow-up) ❑ (5) →End

B. SPECIMEN CONSENT

Restrictions on consent of study specimen *(indicate all that apply):*

		A. Restrictions		B. If yes, please specify:
6.	Use/storage of archived plasma ICT06a	❑Y	❑N	ICT6b _____
7.	Use/storage of archived DNA..... ICT07a	❑Y	❑N	ICT7b _____
8.	Use/storage of archived stool..... ICT8a	❑Y	❑N	ICT8b _____
9.	Use/storage of archived rectal biopsies ICT9a	❑Y	❑N	ICT9b _____
10.	Use/storage of archived colonoscopy images ICT10a	❑Y	❑N	ICT10b _____

IMPACT-III

(English–North America)

A QUALITY OF LIFE QUESTIONNAIRE FOR CHILDREN WITH INFLAMMATORY BOWEL DISEASE

INSTRUCTIONS

Below you will find a questionnaire containing 35 questions for children who have **inflammatory bowel disease (Crohn's disease or ulcerative colitis)**. The questions are about your life with inflammatory bowel disease. Some questions deal with, for example, pains you may suffer from, others are about feelings or worries you may have.

After each question you will see boxes above five possible answers. Please put **a cross in the box above the answer that best fits your answer**.

First an example:
The question is: How afraid are you of tigers?

☐	☐	☐	☒	☐
Not at all afraid	A little afraid	Quite afraid	Afraid	Very much afraid

So, this person is **afraid** of tigers.

☐	☒	☐	☐	☐
Not at all afraid	A little afraid	Quite afraid	Afraid	Very much afraid

This person is **a little afraid** of tigers.

Please answer **all the questions**! If you do not understand a question, ask someone for help.

Good luck with filling in the questionnaire and....many thanks in advance for your efforts!

Contact: Dr. Anthony Otley impact@iwk.nshealth.ca Version: Nov.04

Question 1.	**How much has your stomach been hurting you in the past two weeks?** IMP1

☐	☐	☐	☐	☐
Not at all	Hardly hurting at all	Hurting somewhat	Hurting quite a bit	Hurting very much

Question 2.	**Taking medicines or tablets bothers you** IMP2

☐	☐	☐	☐	☐
Not at all	Hardly bothers at all	Bothers somewhat	Bothers quite a bit	Bothers very much

Question 3.	**How often has your inflammatory bowel disease prevented you from eating what you want in the past two weeks?** IMP3

☐	☐	☐	☐	☐
Never	Rarely	Sometimes	Often	Very often

Question 4.	**How often have you been worrying about having a flare-up (increase of symptoms) in the last two weeks?** IMP4

☐	☐	☐	☐	☐
Never	Rarely	Sometimes	Often	Very often

Question 5.	**How much does it bother you that you have an illness that does not just go away?** IMP5

☐	☐	☐	☐	☐
Not at all	Hardly bothers at all	Bothers somewhat	Bothers quite a bit	Bothers very much

Question 6.	**How much energy did you have during the past two weeks?** IMP6

☐	☐	☐	☐	☐
Very much energy	Quite a bit of energy	Some energy	A little energy	No energy at all

Question 7.	**How do you feel about your weight?** IMP7

☐	☐	☐	☐	☐
I feel great about my weight	I feel good about my weight	I don't feel good or bad about my weight	I feel bad about my weight	I feel awful about my weight

Question 8.	**How has your inflammatory bowel disease affected your family?** IMP8

☐	☐	☐	☐	☐
The effect has been great	The effect has been good	It has not affected our family	The effect has been bad	The effect has been awful

Question 9.	**How often did you have to miss out on certain things (hobbies, play, parties) because of your inflammatory bowel disease in the past two weeks?** IMP9

☐	☐	☐	☐	☐
Never	Rarely	Sometimes	Often	Very often

Question 10.	**How often have you been bothered by diarrhea (loose or frequent bowel movements) in the past two weeks?** IMP10

☐	☐	☐	☐	☐
Never	Rarely	Sometimes	Often	Very often

Question 11.	**How often do you worry about health problems you might have in the future?** IMP11

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Very often

Question 12.	**How often do you think it is unfair that you have inflammatory bowel disease?** IMP12

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Very often

Question 13.	**During the past two weeks, were you ever angry that you have inflammatory bowel disease?** IMP13

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Very often

Question 14.	**Do you think too many rules or limits are placed on you because of your inflammatory bowel disease?** IMP14

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Very often

Question 15.	**How do you feel about the way you look?** IMP15

☐ I think I look great ☐ I think I look good ☐ I don't think I look good or bad ☐ I think I look bad ☐ I think I look awful

Question 16. **Are you embarrassed because of your bowel condition?** IMP16

☐ Not at all | ☐ **Hardly embarrassed at all** | ☐ Embarrassed somewhat | ☐ Embarrassed quite a bit | ☐ Embarrassed very much

Question 17. **Did you have fun during the past two weeks?** IMP17

☐ Very often | ☐ Often | ☐ Sometimes | ☐ Rarely | ☐ Never

Question 18. **Is it harder to make friends because of your inflammatory bowel disease?** IMP18

☐ Not at all harder | ☐ A little harder | ☐ Quite a bit harder | ☐ Much harder | ☐ Very much harder

Question 19. **How often do you worry about your stool (bowel movement) containing blood?** IMP19

☐ Never | ☐ Rarely | ☐ Sometimes | ☐ Often | ☐ Very often

Question 20. **Are you worried you cannot go out on a date or have a boyfriend or girlfriend because of your inflammatory bowel disease?** IMP20

☐ Not at all worried | ☐ Hardly worried at all | ☐ Worried somewhat | ☐ Worried quite a bit | ☐ Worried very much

Question 21. **How often did you feel sick to your stomach in the past two weeks?** IMP21

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Very often

Question 22. **How do you feel about the tests you have to go through?** IMP22

☐ I do not mind them at all ☐ I mind them a tiny bit ☐ I mind them a little ☐ I mind them a lot ☐ I hate them

Question 23. **Do other children bully you or leave you out of things because of your inflammatory bowel disease or its treatment?** IMP23

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Very often

Question 24. **How often do you worry about having an operation?** IMP24

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Very often

Question 25. **In the past two weeks how often were you afraid you may have an accident or not get to the toilet in time?** IMP25

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Very often

Question 26.	**Do you try to keep your inflammatory bowel disease a secret from other people?** IMP26

☐	☐	☐	☐	☐
No, I do not try at all	I don't try much	I try a little	I try hard	Yes, I try very hard

Question 27.	**Does your inflammatory bowel disease make it difficult to travel or go on a holiday?** IMP27

☐	☐	☐	☐	☐
No, not difficult	A little difficult	Quite difficult	Very difficult	Yes, extremely difficult

Question 28.	**How did you feel during the past two weeks?** IMP28

☐	☐	☐	☐	☐
Great	Good	Not good or bad	Bad	Awful

Question 29.	**Are you happy with your life?** IMP29

☐	☐	☐	☐	☐
Yes, very happy	Happy	Not happy or unhappy	Unhappy	Very unhappy

Question 30.	**Do you feel there is someone you can talk to about your inflammatory bowel disease?** IMP30

☐	☐	☐	☐	☐
Always	Often	Sometimes	Rarely	Never

Question 31. **How often did you have to pass gas in the past two weeks?** IMP31

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Very often

Question 32. **How tired have you felt in the past two weeks?** IMP32

☐ Not at all tired ☐ A little tired ☐ Quite tired ☐ Tired ☐ Very tired

Question 33. **How do you feel about your height?** IMP33

☐ I feel great about my height ☐ I feel good about my height ☐ I don't feel good or bad about my height ☐ I feel bad about my height ☐ I feel awful about my height

Question 34. **Does your inflammatory bowel disease get in the way of playing sports the way you would like to?** IMP34

☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always

Question 35. **In the past two weeks how often were you able to go to school ? (If you are in the middle of a school break or the summer holidays, answer as if school was on)** IMP35

☐ Always ☐ Most days ☐ Half the days ☐ A few days ☐ Never

Local Lab Normals Data Form

SITE ID: _____ FORM CODE: LLN VERSION: B 03/08/2013 Contact Occasion _____ SEQ # _____

Date of Form Completion: ___ ___ / LLN0a ___ / ____ ____ ____ ____ Staff Code: LLN0b _____

Instruction: Contact Occasion above is to be coded with CO# associated with the blood draw.

LLN1 1. Lab Name:_____ LLN2 2. ❑(1) Principal Lab for Site ❑(2) Secondary Lab

LLN3 3. Gender: ❑ (1) Male ❑ (2) Female LLN4 4. Age range: ❑(1) <12 ❑(2) ≥12

Test	A. Units			B. Result	
	Conventional (1)	SI (2)	Other (3)	Min.	Max
5. Hemoglobin	❑g/dL	❑g/L LLN5a1	❑ LLN5a2	LLN5b1	LLN5b2
6. Platelet Count	❑10^3/microL	❑10^9/L LLN6a1	❑ LLN6a2	LLN6b1	LLN6b2
7. WBC Count	❑10^3/microL	❑10^9/L LLN7a1	❑ LLN7a2	LLN7b1	LLN7b2
8. Neutrophil	❑%	❑10^9/L LLN8a1	❑ LLN8a2	LLN8b1	LLN8b2
9. Lymphocytes	❑%	❑10^9/L LLN9a1	❑ LLN9a2	LLN9b1	LLN9b2
10. Eosinophil	❑%	❑10^9/L LLN10a1	❑ LL10a2	LLN10b1	LLN10b2
11. ESR	❑ mm/hr	LLN11a1	❑ LLN11a2	LLN11b1	LLN11b2
12. CRP	❑ mg/dL	❑ mg/L LLN12a1	❑ LLN12a2	LLN12b1	LLN12b2
13. hsCRP	❑ mg/dL	❑ mg/L LLN13a1	❑ LLN13a2	LLN13b1	LLN13b2
14. Albumin	❑g/dL	❑g/L LLN14a1	❑ LLN14a2	LLN14b1	LLN14b2
15. BUN	❑mg/dL	❑ LLN15a1 mmol/L	❑ LLN15a2	LLN15b1	LLN15b2
16. Creatinine	❑mg/dL	❑ LLN16a1 micromol/L	❑ LLN16a2	LLN16b1	LLN16b2
17. AST	❑mg/dL	❑ LLN17a1 micromol/L	❑ LLN17a2	LLN17b1	LLN17b2
18. ALT	❑mg/dL	❑ LLN18a1 micromol/L	❑ LLN18a2	LLN18b1	LLN18b2
19. Alk Phos	❑mg/dL	❑ LLN19a1 micromol/L	❑ LLN19a2	LLN19b1	LLN19b2
20. GGT	❑mg/dL	❑ LLN20a1 micromol/L	❑ LLN20a2	LLN20b1	LLN20b2
21. Bilirubin Total	❑mg/dL	❑ LLN21a1 micromol/L	❑ LLN21a2	LLN21b1	LLN21b2
22. Bilirubin Direct	❑mg/dL	❑ LLN22a1 micromol/L	❑ LLN22a2	LLN22b1	LLN22b2
23. Amylase	❑mg/dL	❑ LLN23a1 micromol/L	❑ LLN23b2	LLN23b1	LLN23b2
24. Lipase	❑mg/dL	❑ LLN24a1 micromol/L	❑ LLN24b2	LLN24b1	LLN24b2

PROTECT

Gender: M F

Local Lab Results Form

ID NUMBER: ☐☐☐☐☐☐☐☐

FORM CODE: LLR
VERSION: A 06/18/12

Contact Occasion ☐☐

Seq # ☐☐

Date of Form Completion: ☐☐/☐☐☐/☐☐☐☐ LLR0a

Staff Code: ☐☐☐ LLR0b

FDF # ☐☐ LLR0c

1. Date of Blood Draw (dd / mmm /yyyy) ____ ____ /____ ____ ____/ ____ ____ ____ ____ LLR1

2. Lab Used* _____ LLR2

**If the lab used does NOT appear on the DMS drop down list then also submit a completed reference range form LLN.*

Test	A. Performed			B. Units			C. Results
				Conventional (1)	SI (2)	Other (3)	
	Y	N	U				
3. Hemoglobin	LLR3a ❑	❑	❑	❑g/dL	❑g/L LLR3b1	❑ LLR3b2	LLR3c
4. Platelet Count	LLR4a ❑	❑	❑	❑10^3/microL	❑10^9/L LLR4b1	❑ LLR4b2	LLR4c
5. WBC Count	LLR5a ❑	❑	❑	❑10^3/microL	❑10^9/L LLR5b1	❑ LLR5b2	LLR5c
6. Neutrophil	LLR6a ❑	❑	❑	❑%	❑10^9/L LLR6b1	❑ LLR6b2	LLR6c
7. Lymphocytes	LLR7a ❑	❑	❑	❑%	❑10^9/L LLR7b1	❑ LLR7b2	LLR7c
8. Eosinophil	LLR8a ❑	❑	❑	❑%	❑10^9/L LLR8b1	❑ LLR8b2	LLR8c
9. ESR	LLR9a ❑	❑	❑	❑ mm/hr LLR9b		❑ LLR9b2	LLR9c
10. CRP	LLR10a ❑	❑	❑	❑ mg/dL	❑ mg/L LLR10b1	❑ LLR10b2	LLR10c
11. hsCRP	LLR11a ❑	❑	❑	❑ mg/dL	❑ mg/L LLR11b1	❑ LLR11b2	LLR11c
12. Albumin	LLR12a ❑	❑	❑	❑g/dL	❑g/L LLR12b1	❑ LLR12b2	LLR12c
13. BUN	LLR13a ❑	❑	❑	❑mg/dL	❑ mmol/L LLR13b1	❑ LLR13b2	LLR14c
14. Creatinine	LLR14a ❑	❑	❑	❑mg/dL	❑ micromol/L LLR14b1	❑ LLR14b2	LLR15c
15. AST	LLR15a ❑	❑	❑	❑mg/dL	❑ micromol/L LLR15b1	❑ LLR15b2	LLR316c
16. ALT	LLR16a ❑	❑	❑	❑mg/dL	❑ micromol/L LLR16b1	❑ LLR16b2	LLR17c
17. Alk Phos	LLR17a ❑	❑	❑	❑mg/dL	❑ micromol/L LLR17b1	❑ LLR17b2	LLR18c
18. GGT	LLR18a ❑	❑	❑	❑mg/dL	❑ micromol/L LLR18b1	❑ LLR18b2	LLR19c
19. Bilirubin Total	LLR19a ❑	❑	❑	❑mg/dL	❑ micromol/L LLR19b1	❑ LLR19b2	LLR20c
20. Bilirubin Direct	LLR20a ❑	❑	❑	❑mg/dL	❑ micromol/L LLR20b1	❑ LLR20b2	LLR21c
21. Amylase	LLR21a ❑	❑	❑	❑mg/dL	❑ micromol/L LLR21b1	❑ LLR21b2	LLR22c
22. Lipase	LLR22a ❑	❑	❑	❑mg/dL	❑ micromol/L LLR22b1	❑ LLR22b2	LLR23c

Gender: M F

Medical and EIM Baseline Summary Form

ID NUMBER: ☐☐☐☐☐☐☐ FORM CODE: MES VERSION: B 09/18/2013 Contact Occasion ☐☐ Seq # ☐☐

Date of Form Completion: ☐☐/☐☐/☐☐☐☐ MES0a Staff Code: MES0b ☐

A. Does the participant have a known history of any of the following extra-intestinal manifestations (EIMs)

	N	P	D	U
1. Small Joint Arthritis	❑	❑	❑	❑ MES1
2. Large Joint Arthritis	❑	❑	❑	❑ MES2
3. Ankylosing Spondylitis	❑	❑	❑	❑ MES3
4. Sacroiliitis	❑	❑	❑	❑ MES4
5. Erythema Nodosum	❑	❑	❑	❑ MES5
6. Pyoderma Gangrenosum	❑	❑	❑	❑ MES6
7. Iritis/Uveitis	❑	❑	❑	❑ MES7
8. Autoimmune Hepatitis	❑	❑	❑	❑ MES8
9. Primary Sclerosing Cholangitis	❑	❑	❑	❑ MES9
10. Pancreatitis	❑	❑	❑	❑ MES10
11. DVT/Thromboembolic	❑	❑	❑	❑ MES11
12. Other significant EIMs Specify:_____ _____ MES12a	❑	❑	❑	❑ MES12
13. Other significant EIMs Specify:_____ _____ MES13a	❑	❑	❑	❑ MES13

B. Does the participant have a known history of, or currently suffer from, any of the following medical diagnoses:

	Yes	No	Unknown
14. Rheumatoid Arthritis	❑	❑	❑ MES14
15. Psoriasis	❑	❑	❑ MES15
16. Autoimmune Thyroid Disease	❑	❑	❑ MES16
17. Celiac Disease (Bx proven)	❑	❑	❑ MES17
18. Atopy or Asthma	❑	❑	❑ MES18
19. IDDM	❑	❑	❑ MES19
20. Multiple Sclerosis	❑	❑	❑ MES20
21. Lupus	❑	❑	❑ MES21
22. Other significant medical Specify:_____ _____ MES22a	❑	❑	❑ MES22
23. Other significant medical Specify:_____ _____ MES23a	❑	❑	❑ MES23

N = Never P = First noted >4 weeks from Day 0 D = First Noted within 4 weeks of Day 0 U = Unknown

Gender: M F

Medical and EIM Follow-up Summary Form

ID NUMBER: | | | | | | | |

FORM CODE: MEF
VERSION: B 04/10/2013

Contact Occasion | |

Seq # | |

Date of Form Completion: | | / MEF0a | | / | | | | |

Staff Code: MEF0b | |

FDF # MEF0c | |

Since the last review, has the participant:

A. Reported any *new* extra-intestinal manifestation (EIMs)?

	EIMs	PR* (1)	Y (2)	N (3)	U (4)	If yes ,then approx. Date First Recognized* (a)
MEF1	1. Small Joint Arthritis	❑	❑	❑	❑	MEF1a __ __/__ __ __/__ __ __ __
MEF2	2. Large Joint Arthritis	❑	❑	❑	❑	MEF2a __ __/__ __ __/__ __ __ __
MEF3	3. Ankylosing Spondylitis	❑	❑	❑	❑	MEF3a __ __/__ __ __/__ __ __ __
MEF4	4. Sacroiliitis	❑	❑	❑	❑	MEF4a __ __/__ __ __/__ __ __ __
MEF5	5. Erythema Nodosum	❑	❑	❑	❑	MEF5a __ __/__ __ __/__ __ __ __
MEF6	6. Pyoderma Gangrenosum	❑	❑	❑	❑	MEF6a __ __/__ __ __/__ __ __ __
MEF7	7. Iritis/Uveitis	❑	❑	❑	❑	MEF7a __ __/__ __ __/__ __ __ __
MEF8	8. Autoimmune Hepatitis	❑	❑	❑	❑	MEF8a __ __/__ __ __/__ __ __ __
MEF9	9. Primary Sclerosing Cholangitis	❑	❑	❑	❑	MEF9a __ __/__ __ __/__ __ __ __
MEF10	10. Pancreatitis	❑	❑	❑	❑	MEF10a __ __/__ __ __/__ __ __ __
MEF11	11. DVT/Thromboembolic	❑	❑	❑	❑	MEF11a __ __/__ __ __/__ __ __ __
MEF12	12. Other significant EIMs Specify: MEF12b	❑	❑	❑	❑	MEF12a __ __/__ __ __/__ __ __ __
MEF13	13. Other significant EIMs Specify: MEF13b	❑	❑	❑	❑	MEF13a __ __/__ __ __/__ __ __ __

B. Reported any *new* additional medical diagnoses?

	Medical Diagnoses	PR* (1)	Y (2)	N (3)	U (4)	If yes ,then approx. Date First Recognized* (a)
MEF14	14. Rheumatoid Arthritis	❑	❑	❑	❑	MEF14a __ __/__ __ __/__ __ __ __
MEF15	15. Psoriasis	❑	❑	❑	❑	MEF15a __ __/__ __ __/__ __ __ __
MEF16	16. Autoimmune Thyroid Disease	❑	❑	❑	❑	MEF16a __ __/__ __ __/__ __ __ __
MEF17	17. Celiac Disease (Bx proven)	❑	❑	❑	❑	MEF17a __ __/__ __ __/__ __ __ __
MEF18	18. Atopy/Asthma	❑	❑	❑	❑	MEF18a __ __/__ __ __/__ __ __ __
MEF19	19. IDDM	❑	❑	❑	❑	MEF19a __ __/__ __ __/__ __ __ __
MEF20	20. Multiple Sclerosis	❑	❑	❑	❑	MEF20a __ __/__ __ __/__ __ __ __
MEF21	21. Lupus	❑	❑	❑	❑	MEF21a __ __/__ __ __/__ __ __ __
MEF22	22. Other significant medical Specify: MEF22b	❑	❑	❑	❑	MEF22a __ __/__ __ __/__ __ __ __
MEF23	23. Other significant medical Specify: MEF23b	❑	❑	❑	❑	MEF23a __ __/__ __ __/__ __ __ __

**PR = Previously Recognized* *Y = Yes* *N = No* *U = Unknown*

PROTECT

Gender: M F

Post-Colectomy Follow-up Form

ID NUMBER: ☐☐☐☐☐☐☐☐ FORM CODE: PCF VERSION: A 06/18/12 Contact Occasion ☐☐ Seq # ☐☐

Date of Form Completion: ☐☐/☐☐☐/☐☐☐☐ PCF0a Staff Code: ☐☐☐ PCF0b FDF # ☐☐ PCF0c

A. Pouch Details

Current Status

1. Subtotal colectomy with diverting ileostomy? ..... ❑Yes→Q10 ❑No PCF1
2. Subtotal colectomy, Pouch Formation, Diverting ileostomy? ..... ❑Yes ❑No→Q3 PCF2
   a. Has the participant undergone pouch (re)-formation since the last review: ..... ❑Yes ❑No→Q9 PCF2a
   b. Date of Pouch Formation: (dd/mmm/yyyy) ___ ___ / ___ ___ ___ / ___ ___ ___ ___→Q9 PCF2b
3. Subtotal colectomy, IPAA? ..... ❑Yes ❑No →Q4 PCF3
   a. Has the participant undergone ostomy closure since the last review? ..... ❑Yes ❑No →Q6 PCF3a
   b. Date of Ostomy Closure: (dd/mmm/yyyy) ___ ___ / ___ ___ ___ / ___ ___ ___ ___→Q6 PCF3b
4. Previous IPAA with subsequent pouch excision and permanent ostomy? ..... ❑Yes ❑No →Q5 PCF4
   a. Has the participant undergone pouch excision since the last review: ..... ❑Yes ❑No →Q10 PCF4a
   b. Reason for excision: _____ PCF4b
   c. Date of Pouch excision: (dd/mmm/yyyy) ___ ___ / ___ ___ ___ / ___ ___ ___ ___→Q10 PCF5c
5. Other: ..... ❑Yes ❑No PCF5
   If yes, give description: _____ PCF5a

B. Pouch Function

6. Current Pouch Function (or function prior to pouch excision where applicable)
   a. Stool Frequency per 24 hour period: ..... 1. # during the daytime PCF6a1 2. #overnight PCF6a2
   b. Soiling or Seepage during the day? ..... ❑Yes ❑No PCF6b
   c. Soiling or Seepage during the night? ..... ❑Yes ❑No PCF6c
   d. Bleeding: ..... ❑ (1) None ❑ (2) Rare ❑ (3) Present ❑(4) Daily PCF6d
   e. Urgency (unable to defer stool evacuation by >30 min): ..... ❑Yes ❑No PCF6e
   f. Evacuation Difficulties (> 15 min spent in toilet at one time) ..... ❑Yes ❑No PCF6f
   g. Perianal Soreness: ..... ❑ (1) None ❑ (2) Occasional ❑ (3) Frequent PCF6g
7. Clinical Diagnosis of Pouchitis since last review: ..... ❑Yes ❑No→Q8 PCF7
   a. Est. date symptoms started: (dd/mmm/yyyy) ___ ___ / ___ ___ ___ / ___ ___ ___ ___ PCF7a
   b. Commenced specific therapy for Pouchitis? ..... ❑Yes→ATF, SMF, SLR ❑No PCF7b
   c. Est date of resolution: (1) (dd/mmm/yyyy) ___ ___ / ___ ___ ___ / ___ ___ ___ ___ ❑ (2) Not yet resolved PCF7c
8. Endoscopic and/or Histologic evidence of Pouchitis since last review? ..... ❑Yes ❑No→Q9 PCF8
   a. Mucosal Edema/Granularity/Friability? ..... ❑Yes ❑No PCF8a
   b. Mucosal Exudates/Ulceration? ..... ❑Yes ❑No PCF8b
   c. Mild/Mod polymorph infiltration? ..... ❑Yes ❑No PCF8c
   d. Severe polymorph infiltration + crypt abscesses? ..... ❑Yes ❑No PCF8d

C. Pouch Complications

9. Pouch Related Complications experienced since the last review:
   a. Anastomotic dehiscence: PCF9a ..... ❑Yes ❑No
   b. Pouch-Anal fistula: PCF9b ..... ❑Yes ❑No
   c. Pouch Leakage: PCF9c ..... ❑Yes ❑No
   d. Pouch-Vaginal fistula: ..... ❑Yes ❑No PCF9d
   e. Peri-pouch abscess: ..... ❑Yes ❑No PCF9e
   f. Anal canal stricture: ..... ❑Yes ❑No PCF9f
10. Small Bowel and other complications since the last review:
   a. Small bowel obstruction: PCF10a ..... ❑Yes ❑No
   b. Renal Stones PCF10b ..... ❑Yes ❑No
   c. Significant Dehydration needing IV therapy: ..... ❑Yes ❑No PCF10c
   d. Findings diagnostic for Crohn's Disease ..... ❑Yes ❑No PCF10d

Gender: M F

PUCAI Form

ID NUMBER: | | | | | | | |

FORM CODE: PUC
VERSION: A 06/26/12

Contact Occasion | |

Seq # | |

Date of Contact: | | / | | | | / | | PUC0a | |

Staff Code: | | PUC0b | |

FDF # | | PUC0c

Instructions: Each of the items below should be scored after performing a history and evaluation. If performed on the day of colonoscopy, stool frequency refers to the 24 hour period *prior* to commencing colonoscopy bowel prep. Ideally, participants should be off any anti-diarrheal medicines for at least 48 hours prior to assessment.

1. Date of assessment: (dd/mmm/yyyy) ____ ____ /____ ____ ____/ ____ ____ ____ ____ PUC1

2. Assessment Type: ..... ❑ Telephone ❑ Clinic Visit PUC2

3. Assessors Initials: ..... ____ ____ ____ PUC3 **3a.** Assessor qualifications: ❑ MD ❑ RN ❑ Other PUC3a

PUCAI ITEM	POINTS	User's Guide
4. Abdominal pain: PUC4 No pain Pain can be ignored Pain cannot be ignored	0 ❑ 5 ❑ 10 ❑	Time period for evaluation: • Answers should reflect a daily average of the last 2 days. • If clinical conditions are changing rapidly (eg, during intense intravenous therapy), the most recent 24 hours should be considered. • For participants undergoing colonoscopy, answers should reflect the 2 days before bowel clean out was started. Rectal Bleeding: • "Large amount" should be selected if large amount of blood is present in most stools. Number of stools per 24 hours • Clusters of several small stools over a very short period of time that could be related to tenesmus or incomplete evacuation should be considered as 1 stool. Activity Level • Occasional limitation of activity = could attend school or equivalent but reduced activity (eg, attends school but does not play at breaks); • Severe restricted activity = could not attend school or equivalent activity.
5. Rectal Bleeding PUC5 None Small amount only in less than 50% of stools Small amount with most stools Large amount (>50% of the stool content)	0 ❑ 10 ❑ 20 ❑ 30 ❑	
6. Stool consistency of most stools PUC6 Formed Partially formed Completely unformed	0 ❑ 5 ❑ 10 ❑	
7. Number of stools per 24 hours PUC7 0-2 3-5 6-8 >8	0 ❑ 5 ❑ 10 ❑ 15 ❑	
8. Nocturnal stools (any episode causing awakening) PUC8 No Yes	0 ❑ 10 ❑	
9. Activity level PUC9 No limitation of activity Occasional limitation of activity Severe restricted activity	0 ❑ 5 ❑ 10 ❑	
10. SUM OF PUCAI (0-85) PUC10 Inactive disease: PUCAI<10 Mild activity PUCAI 10-34 Moderate activity PUCAI 35-64 Severe activity PUCAI ≥65	____ ____	

11. Was a sigmoidoscopy or the equivalent performed today? ❑Y→EEF ❑ N PUC11

12. Stool Frequency (per day) PUC12 ❑ (1) Normal for participant ❑ (2) 1 - 2 more than normal ❑ (3) 3 - 4 more than normal ❑ (4) >= 5 more than normal	**13. Rectal Bleeding** PUC13 ❑ (1) No Blood Seen ❑ (2) Streaks of blood with stool, less than half the time ❑ (3) Obvious blood with stool most of the time ❑ (4) Blood alone passes

Gender: M F

Second Line / Rescue Therapy Form

ID NUMBER: | | | | | | | |

FORM CODE: SLR
VERSION: A 02/15/2013

Contact Occasion | | |

Seq # | | |

Date of Form Completion: | | / | | | | / | | | SLR0a | |

Staff Code: SLR0b | | |

FDF # | | SLR0c

A. Record of Immunomodulator Therapies

1. Has an immunomodulator therapy been commenced, ongoing, or stopped, since the last review?.. ❑Y ❑ N→Q6 SLR1

Immunomodulators	A. Since Last Review? Not Received (1)	Ongoing (2)	Commenced →AMT (3)	B. Current Status Stopped →AMT (1)	New Dose →AMT (2)	Same Dose (3)	C. Current Dose (mg)	D. Freq
2. Azathioprine	❑→Q3	❑	❑	❑→Q3 SLR2a	❑ SLR2b	❑	SLR2c	N/A SLR2d
3. Mercaptopurine	❑→Q4	❑	❑	❑→Q4 SLR3a	❑ SLR3b	❑	SLR3c	N/A SLR3d
4. Methotrexate (SC/IM)	❑→Q5	❑	❑	❑→Q5 SLR4a	❑ SLR4b	❑	SLR4c	SLR4d
5. Methotrexate (Oral)	❑→Q6	❑	❑	❑→Q6 SLR5a	❑ SLR5b	❑	SLR5c	SLR5d

B. Record of Calcineurin Inhibitor Therapies

6. Have any calcineurin Inhibitors been commenced, ongoing, or stopped since last review? ..... ❑Y ❑ N→Q9 SLR6

Calcineurin Inhibitors	A. Since Last Review? Not Received	Ongoing	Commenced →AMT	B. Current Status Stopped →AMT	New Dose →AMT	Same Dose	C. Current Dose (mg)
7. Tacrolimus	❑→Q8	❑	❑	❑→Q8 SLR7a	❑ SLR7b	❑	SLR7c
8. Cyclosporin	❑→Q9	❑	❑	❑→Q9 SLR8b	❑ SLR8b	❑	SLR8c

C. Record of Biologic Agents

9. Have any biologic agents been commenced, ongoing, or stopped since last review?..... ❑Y ❑ N→Q15 SLR9

10. Infliximab status since last review: .....❑ (1) Not Received→Q12 ❑ (2) Ongoing ❑ (3) Commenced→AMT SLR10

11. Please provide the following data for each individual dose of infliximab:

	1. Date (dd/mmm/yyyy)	2. Dose (mg)	3. Subsequent Dose? Y→AMT	N
a.	SLR11a1	SLR11a2	❑	❑→Q12 SLR11a3
b.	SLR11b1	SLR11b2	❑	❑→Q12 SLR11b3
c.	SLR11c1	SLR11c2	❑	❑→Q12 SLR11c3
d.	SLR11d1	SLR11d2	❑	❑→Q12 SLR11d3
e.	SLR11e1	SLR11e2	❑	❑→Q12 SLR11e3
f.	SLR11f1	SLR11f2	❑	❑→Q12 SLR11f3

12. Adalimumab status since last review: .....❑ (1) Not Received→Q14 ❑ (2) Ongoing ❑ (3) Commenced→AMT SLR12

13. Please provide the following data for individual doses of Adalimumab during induction and prescription changes:

	1. Date (dd/mmm/yyyy)	2. Dose (mg)	3. Freq.	4. Subsequent Dose/Freq Change? Y→AMT	N
a.	SLR13a1	SLR13a2	SLR13a3	❑	❑→Q14 SLR13a4
b.	SLR13b1	SLR13b2	SLR13b3	❑	❑→Q14 SLR13b4
c.	SLR13c1	SLR13c2	SLR13c3	❑	❑→Q14 SLR13c4
d.	SLR13d1	SLR13d2	SLR13c3	❑	❑→Q14 SLR13d4
e.	SLR13e1	SLR13e2	SLR13e3	❑	❑→Q14 SLR13ef
f.	SLR13f1	SLR13f2	SLR13f3	❑	❑→Q14 SLR13f4

14. Has a biologic agent been formally ceased since the last visit? .....❑Y→AMT ❑ N SLR14

15. Have any drug or metabolite levels been taken since the last visit? .....❑Y→ALF ❑ N SLR15

PROTECT
Predicting Response to Standardized Pediatric Colitis Therapy

Gender: M F

Serious Adverse Event Form

ID NUMBER: ☐☐☐☐☐☐☐ FORM CODE: SAE VERSION: A 02/14/12 Contact Occasion ☐☐ SEQ # ☐☐

Date of Contact: ☐☐/☐☐☐/☐☐☐☐ SAE0a Staff Code: ☐☐☐ SAE0b

Instructions: This form is to be completed for all serious adverse events reported during the study. Seriousness is a regulatory definition and should not be confused with severity. SAEs must be reported ASAP, SAEs unexpected and a suspected adverse reaction must be reported to DCC immediately.

A. Serious Adverse Event Information

1. Date of Onset: (dd/mmm/yyyy): ___ ___ /___ ___ ___/ ___ ___ ___ ___ SAE1

2. Event Diagnosis_____ SAE2

3. Criteria for definition of SAE (check all that apply): SAE3

a. ❑ Death
b. ❑ Life threatening
c. ❑ In-patient hospitalization or prolongation
d. ❑ Persistent or significant disability/incapacity
g. ❑ Congenital anomaly /birth defect
h. ❑ Other medically important condition
i. ❑ Other, specify SAE3i1 _____

4. Was this an unexpected adverse event ..... ❑Y ❑N SAE4

5. Is the event due to progression of underlying illness ..... ❑Y ❑N SAE5

6. Relationship of serious adverse event to study medication *(check one)*: SAE6

Unrelated (clearly not related to intervention) ..... ❑ (1)
Unlikely related ..... ❑ (2)
Possibly (may be related) ..... ❑ (3)
Definite (clearly related to intervention) ..... ❑ (4)

7. Outcome of event: SAE7

Resolved ..... ❑ (1)
Recovered with minor sequelae ..... ❑ (2)
Recovered with major sequelae ..... ❑ (3)
Condition still present ..... ❑ (4) skip 8
Condition continues to worsen ..... ❑ (5) skip 8
Patient died ..... ❑ (6)

8. Date of event resolution or death (mm/dd/yyyy): ___ ___ /___ ___ ___/ ___ ___ ___ ___ SAE8

9. Describe more fully the serious adverse event (a summary of signs, symptoms, diagnosis, treatment of event, concurrent treatment, other relevant medical history, include the point of the study in which the event occurred). SAE9

_____

_____

_____

B. Administrative Information

10. Form Completion Date (dd/mmm/yyyy): ___ ___ /___ ___ ___/ ___ ___ ___ ___ SAE10

11. Initials of person completing report: ____ ____ ____ SAE11

12. Signature of Principal Investigator: _____ SAE12

Gender: M F

Serious Adverse Event Form

ID NUMBER: ☐☐☐☐☐☐☐ FORM CODE: SAE VERSION: B 05/07/13 Contact Occasion ☐☐ Seq # ☐☐

Date of Form Completion: ☐☐/☐☐/☐☐☐☐ SAE0a Staff Code: SAE0b ☐ FDF # ☐☐ SAE0c

A. Serious Adverse Event Information

1. Date of Onset: (dd/mmm/yyyy): ___ ___ /___ ___ ___/ ___ ___ ___ ___ SAE1
2. Event Diagnosis_____ SAE2
3. Criteria for definition of SAE:
   - a. Death ..... SAE3a ❑Y ❑N
   - b. Life threatening ..... SAE3b ❑Y ❑N
   - SAE3c c. In-patient hospitalization or prolongation ..... ❑Y→HDF ❑N
   - d. Persistent or significant disability/incapacity ..... ❑Y ❑N SAE3d
   - e. Congenital anomaly /birth defect..... ❑Y ❑N SAE3e
   - f. Other medically important condition ..... ❑Y ❑N SAE3f
   - g. Other ..... ❑Y ❑N SAE3g
     - 1. Specify:_____ SAE3g1
4. Was this an unexpected adverse event..... ❑Y ❑N SAE4
5. Is the event due to progression of underlying illness..... ❑Y ❑N-SAE5

B. Medication(s) considered (potentially) implicated in this event:

Drug	A. On this medication at time of SAE onset?		B. Relationship of SAE to treatment (Check one box for each medication being taken at SAE onset)			
	Yes	No	Unrelated	Unlikely related	Possibly	Definite
6. Mesalamine	☐	☐→7a SAE6a	☐	☐	☐	☐ SAE6b
7. Corticosteroid	☐	☐ →8a SAE7a	☐	☐	☐	☐ SAE7b
8. Thiopurine	☐	☐ →9a SAE8a	☐	☐	☐	☐ SAE8b
9. Methotrexate	☐	☐ →10a SAE9a	☐	☐	☐	☐ SAE9b
10. Calcineurin Inhibitor	☐	☐ →11a SAE10a	☐	☐	☐	☐ SAE10b
11. Anti-TNF agent	☐	☐ →12 SAE11a	☐	☐	☐	☐ SAE11b

12. Outcome of event: SAE12
    - ❑ (1) Resolved
    - ❑ (2) Recovered with minor sequelae
    - ❑ (3) Recovered with major sequelae
    - ❑ (4) Condition still present→Q14
    - ❑ (5) Condition continues to worsen→Q14
    - ❑ (6) Patient died
13. Date of event resolution or death (mm/dd/yyyy): ___ ___ /___ ___ ___/ ___ ___ ___ ___ SAE13

14. Describe more fully the serious adverse event (a summary of signs, symptoms, diagnosis, treatment of event, concurrent treatment, other relevant medical history, include the point of the study in which the event occurred). SAE14a

C. Administrative Information

15. Form Completion Date (dd/mmm/yyyy): ___ ___ /___ ___ ___/ ___ ___ ___ ___ SAE15

16. Initials of person completing report: ____ ____ ____ SAE16

17. Signature of Principal Investigator: _____ SAE17

Gender: M F

Side Effects/Adverse Events Form

ID NUMBER: ☐☐☐☐☐☐☐ FORM CODE: SEF VERSION:A 02/15/2013 Contact Occasion ☐☐ Seq # ☐☐

Date of Contact: ☐☐/☐☐/☐☐ SEF0a ☐ Staff Code: SEF0b ☐☐ FDF # ☐☐ SEF0c

Instructions: Each new or ongoing event is reported by recording the highest **Severity Rating:**

- **Mild adverse event:** Awareness of sign, symptom, or event, but easily tolerated.
- **Moderate adverse event:** Discomfort enough to cause interference with usual activity and may warrant intervention.
- **Severe adverse event:** Incapacitating with inability to do usual activities or significantly affects clinical status, and warrants intervention. **A severe rating is not the same as a serious adverse event which must also be reported on the SAE form.**

1. Abdominal Pain: ❑ (1) None→Q2 ❑ (2) Mild ❑ (3) Moderate ❑ (4) Severe SEF1
- **a.** Frequency since the last study contact? ❑ (1) Rarely ❑ (2) Sometime ❑ (3) Often ❑ (4) N/A SEF1a
- **b.** Caused by a study medication? ❑ (1) Yes ❑ (2) No ❑ (3) Don't Know ❑ (4) N/A SEF1b
- **c.** Seek medical care for this problem? ❑ (1) No ❑ (2) Clinic/ER ❑ (3) Study ❑ (4) Hospital→SAE SEF1c

2. Diarrhea: ❑ (1) None→Q3 ❑ (2) Mild ❑ (3) Moderate ❑ (4) Severe SEF2
- **a.** Frequency since the last study contact? ❑ (1) Rarely ❑ (2) Sometime ❑ (3) Often ❑ (4) N/A SEF2a
- **b.** Caused by a study medication? ❑ (1) Yes ❑ (2) No ❑ (3) Don't Know ❑ (4) N/A SEF2b
- **c.** Seek medical care for this problem? ❑ (1) No ❑ (2) Clinic/ER ❑ (3) Study ❑ (4) Hospital→SAE SEF2c

3. Dyspepsia: ❑ (1) None→Q4 ❑ (2) Mild ❑ (3) Moderate ❑ (4) Severe SEF3
- **a.** Frequency since the last study contact? ❑ (1) Rarely ❑ (2) Sometime ❑ (3) Often ❑ (4) N/A SEF3a
- **b.** Caused by a study medication? ❑ (1) Yes ❑ (2) No ❑ (3) Don't Know ❑ (4) N/A SEF3b
- **c.** Seek medical care for this problem? ❑ (1) No ❑ (2) Clinic/ER ❑ (3) Study ❑ (4) Hospital→SAE SEF3c

4. Headache: ❑ (1) None→Q5 ❑ (2) Mild ❑ (3) Moderate ❑ (4) Severe SEF4
- **a.** Frequency since the last study contact? ❑ (1) Rarely ❑ (2) Sometime ❑ (3) Often ❑ (4) N/A SEF4a
- **b.** Caused by a study medication? ❑ (1) Yes ❑ (2) No ❑ (3) Don't Know ❑ (4) N/A SEF4b
- **c.** Seek medical care for this problem? ❑ (1) No ❑ (2) Clinic/ER ❑ (3) Study ❑ (4) Hospital→SAE SEF4c

5. Nausea: ❑ (1) None→Q6 ❑ (2) Mild ❑ (3) Moderate ❑ (4) Severe SEF5
- **a.** Frequency since the last study contact? ❑ (1) Rarely ❑ (2) Sometime ❑ (3) Often ❑ (4) N/A SEF5a
- **b.** Caused by a study medication? ❑ (1) Yes ❑ (2) No ❑ (3) Don't Know ❑ (4) N/A SEF5b
- **c.** Seek medical care for this problem? ❑ (1) No ❑ (2) Clinic/ER ❑ (3) Study ❑ (4) Hospital→SAE SEF5c

6. Rash: ❑ (1) None→Q7 ❑ (2) Mild ❑ (3) Moderate ❑ (4) Severe SEF6
- **a.** Frequency since the last study contact? ❑ (1) Rarely ❑ (2) Sometime ❑ (3) Often ❑ (4) N/A SEF6a
- **b.** Caused by a study medication? ❑ (1) Yes ❑ (2) No ❑ (3) Don't Know ❑ (4) N/A SEF6b
- **c.** Seek medical care for this problem? ❑ (1) No ❑ (2) Clinic/ER ❑ (3) Study ❑ (4) Hospital→SAE SEF6c

7. Vomiting: ❑ (1) None→Q8 ❑ (2) Mild ❑ (3) Moderate ❑ (4) Severe SEF7
- **a.** Frequency since the last study contact? ❑ (1) Rarely ❑ (2) Sometime ❑ (3) Often ❑ (4) N/A SEF7a
- **b.** Caused by a study medication? ❑ (1) Yes ❑ (2) No ❑ (3) Don't Know ❑ (4) N/A SEF7b
- **c.** Seek medical care for this problem? ❑ (1) No ❑ (2) Clinic/ER ❑ (3) Study ❑ (4) Hospital→SAE SEF7c

8. Have you had any other health problems since your last visit? ❑ Y*→SEG ❑ N SEF8

**Record only those problems that the participant, family, or Investigator considers a potential medication side effect or related to UC.*

Gender: M F

Side Effects/General Form

ID NUMBER: | | | | | | | |

FORM CODE: SEG
VERSION: A 02/11/2013

Contact Occasion | |

Seq # | |

Date of Contact: | | / | | | / | | SEG0a | |

Staff Code: SEG0b | | |

FDF # SEG0c | |

Instructions: Each new or ongoing event is reported by recording the highest **Severity Rating:**

- **Mild adverse event:** Awareness of sign, symptom, or event, but easily tolerated.
- **Moderate adverse event:** Discomfort enough to cause interference with usual activity and may warrant intervention.
- **Severe adverse event:** Incapacitating with inability to do usual activities or significantly affects clinical status, and warrants intervention. **A severe rating is not the same as a serious adverse event which must also be reported on the SAE form.**

1. Health Event/Problem: _____ SEG1

a. Severity of Event: ..... ❑ (1) Mild ❑ (2) Moderate ❑ (3) Severe SEG1a

b. Frequency since the last study contact? ..... ❑ (1) Rarely ❑ (2) Sometime ❑ (3) Often ❑ (4) N/A SEG1b

c. Caused by a study medication? ..... ❑ (1) Yes ❑ (2) No ❑ (3) Don't Know ❑ (4) N/A SEG1c

d. Seek medical care for this problem? ..... ❑ (1) No ❑ (2) Clinic/ER ❑ (3) Study ❑ (4)Hospital→ SAE SEG1d

e. Are there any other health problems/events to report? ..... ❑ Yes ❑ No→ End SEG1e

2. Health Event/Problem: _____ SEG2

a. Severity of Event: ..... ❑ (1) Mild ❑ (2) Moderate ❑ (3) Severe SEG2a

b. Frequency since the last study contact? ..... ❑ (1) Rarely ❑ (2) Sometime ❑ (3) Often ❑ (4) N/A SEG2b

c. Caused by a study medication? ..... ❑ (1) Yes ❑ (2) No ❑ (3) Don't Know ❑ (4) N/A SEG2c

d. Seek medical care for this problem? ..... ❑ (1) No ❑ (2) Clinic/ER ❑ (3) Study ❑ (4)Hospital→ SAE SEG2d

e. Are there any other health problems/events to report? ..... ❑ Yes ❑ No→ End SEG2e

3. Health Event/Problem: _____ SEG3

a. Severity of Event: ..... ❑ (1) Mild ❑ (2) Moderate ❑ (3) Severe SEG3a

b. Frequency since the last study contact? ..... ❑ (1) Rarely ❑ (2) Sometime ❑ (3) Often ❑ (4) N/A SEG3b

c. Caused by a study medication? ..... ❑ (1) Yes ❑ (2) No ❑ (3) Don't Know ❑ (4) N/A SEG3c

d. Seek medical care for this problem? ..... ❑ (1) No ❑ (2) Clinic/ER ❑ (3) Study ❑ (4)Hospital→ SAE SEG3d

e. Are there any other health problems/events to report? ..... ❑ Yes ❑ No→ End SEG3e

4. Health Event/Problem: _____ SEG4

a. Severity of Event: ..... ❑ (1) Mild ❑ (2) Moderate ❑ (3) Severe SEG4a

b. Frequency since the last study contact? ..... ❑ (1) Rarely ❑ (2) Sometime ❑ (3) Often ❑ (4) N/A SEG4b

c. Caused by a study medication? ..... ❑ (1) Yes ❑ (2) No ❑ (3) Don't Know ❑ (4) N/A SEG4c

d. Seek medical care for this problem? ..... ❑ (1) No ❑ (2) Clinic/ER ❑ (3) Study ❑ (4)Hospital→ SAE SEG4d

e. Are there any other health problems/events to report? ..... ❑ Yes ❑ No→ End SEG4e

5. Health Event/Problem: _____ SEG5

a. Severity of Event: ..... ❑ (1) Mild ❑ (2) Moderate ❑ (3) Severe SEG5a

b. Frequency since the last study contact? ..... ❑ (1) Rarely ❑ (2) Sometime ❑ (3) Often ❑ (4) N/A SEG5b

c. Caused by a study medication? ..... ❑ (1) Yes ❑ (2) No ❑ (3) Don't Know ❑ (4) N/A SEG5c

d. Seek medical care for this problem? ..... ❑ (1) No ❑ (2) Clinic/ER ❑ (3) Study ❑ (4)Hospital→ SAE SEG5d

e. Are there any other health problems/events to report? ..... ❑ Yes ❑ No→ End SEG5e

If yes, then please complete an additional SEG form and increment the sequence number.

Gender: M F

Site Biopsy Histology Score Form

ID NUMBER: | | | | | | | |

FORM CODE: SBH
VERSION: A 07/16/12

Contact Occasion | |

Seq # | |

Date of Form Completion: | | / | | | | / | | | SBH0a

Staff Code: | | SBH0b

FDF # | | SBH0c

1. Reviewer's Identifier: __ __ __ SBH1

2. Date of rectal biopsy (dd/mmm/yyyy): __ __ / __ __ __ / __ __ __ __ SBH2

3. Overall Assessment of Inflammation in **Rectum** only: ❑ Inflammation ❑ No Inflammation→ Q4 SBH3

3a. Chronic Inflammation (one response): SBH3a
- No/mild chronic Inflammation ..... ❑ (1)
- Moderate infiltrate in lamina propria..... ❑ (2)
- Marked infiltrate in lamina propria..... ❑ (3)

3b. Acute Inflammation (one response): SHB3b
- No acute inflammation ..... ❑ (1)
- Mild acute – no crypt abscesses ..... ❑ (2)
- Moderate acute – few crypt abscesses ..... ❑ (3)
- Marked acute – many crypt abscesses ..... ❑ (4)

4. Assessment of any **Non-Rectal** Biopsies:

	Present (1)	Absent (2)	
a. Ulcer/Erosion	❑	❑	SBH4a
b. Crypt distortion/atrophy	❑	❑	SBH4b
c. Surface villiform changes	❑	❑	SBH4c
d. Basal plasmacytosis	❑	❑	SBH4d
e. Basal lymphoid aggregates	❑	❑	SBH4e
f. Paneth cell metaplasia	❑	❑	SBH4f
g. Granuloma	❑	❑	SHB4g

5. Assessment of any **Terminal Ileal** Biopsies: ❑ Available ❑ Not Available→ END SBH5

	Present (1)	Absent (2)	
a. Acute inflammation	❑	❑	SBH5a
b. Chronic inflammation	❑	❑	SBH5b
c. Normal villi	❑	❑	SBH5c
d. Blunted villi	❑	❑	SBH5d
e. Absent villi	❑	❑	SBH5e
f. Granuloma	❑	❑	SBH5f

Discard and Destroy this portion of form once data has been recorded:

First Name:
Family Name:
MRN Identifier:

PROTECT
Predicting Response to Standardized Pediatric Colitis Therapy

Gender: M F

Specimen Collection Form

ID NUMBER: ☐☐☐☐☐☐☐

FORM CODE: SCF
VERSION: A 03/01/12

Contact Occasion ☐☐

SEQ # ☐☐

Date of Form Completion: ☐☐/☐☐☐/☐☐☐☐ SCF0a

Staff Code: ☐☐☐ SCF0b

Instructions: Each of the items below should be scored after performing a history and evaluation. If performed on the day of colonosocopy, stool frequency refers to the 24 hour period *prior* to commencing colonoscopy bowel prep. Ideally, patients should be off any anti-diarrheal medicines for at least 48 hours prior to assessment.

A. Study Specific Samples to be collected

1. **Orange Top:** ❑*Will not be collected* →Q2 ❑*Requested*→Q2 ❑*Collected* ❑*Shipped* SCF1

   a. Date Collected: __ __/ __ __ __/ __ __ __ __ (dd/mmm/yyyy) SCF1a b. Date Shipped: __ __/ __ __ __/ __ __ __ __ (dd/mmm/yyyy) SCF1b c. ID: _____ SCF1c

2. **Purple Top:** ❑*Will not be collected* →Q3 ❑*Requested*→Q3 ❑*Collected* ❑*Shipped* SCF2

   a. Date Collected: __ __/ __ __ __/ __ __ __ __ (dd/mmm/yyyy) SCF2a b. Date Shipped: __ __/ __ __ __/ __ __ __ __ (dd/mmm/yyyy) SCF2b c. ID: _____ SCF2a

3. **Formalin (1Bx for Histopathology):** ❑*Will not be collected* →Q4 ❑*Requested*→Q4 ❑*Collected* ❑*Shipped* SCF3

   a. Date Collected: __ __/ __ __ __/ __ __ __ __ (dd/mmm/yyyy) SCF3a b. Date Shipped: __ __/ __ __ __/ __ __ __ __ (dd/mmm/yyyy) SCF3b c. ID: _____ SCF3c

B. Mucosal Biopsy Sample Collection

4. **RNALater (upto 3 Bx for genetic analaysis) Collected:** ❑ *No* →End ❑ *Yes* →Q4a SCF4

   a. Date Collected: __ __/ __ __ __/ __ __ __ __ (dd/mmm/yyyy) →Q5 SCF4a

   b. Biopsy #1: ❑*Collected* ❑ *Shipped* →Q7 SCF4b

   c. Sample ID: _____ SCF4c

5. **Rectal Biopsy #2:** ❑*Will not be collected* →End ❑*Collected* ❑*Shipped*→Q7 SCF5

   a. Sample ID: _____ SCF5a

6. **Rectal Biopsy #3:** ❑*Will not be collected* →End ❑*Collected* ❑*Shipped*→Q7 SCF6

   a. Sample ID: _____ SCF6a

7. **Date Shipped:** __ __/ __ __ __/ __ __ __ __ (dd/mmm/yyyy) SCF7

Specimen Collection Form

Participant ID Barcode Here

ID NUMBER: | | | | | | | |

FORM CODE: SCF
VERSION: B 12/16/2013

Contact Occasion | | |

Seq # | | |

Date of Contact: | | / | | | / | | | | SCF0a

Staff Code: | | | | SCF0b

FDF # | | | SCF0c

A. Study Specific Blood Sample Collection

1. Orange Top: (check current status): SCF1
   - ❑ (1) Will not be collected →Q2
   - ❑ (2) Requested→Q2
   - ❑ (3) Collected → 1a. Date collected (dd/mmm/yyyy): __ __/ __ __ __/ __ __ __ __ SCF1a
   - ❑ (4) Shipped → 1b. Date Shipped (dd/mmm/yyyy): __ __/ __ __ __/ __ __ __ __ SCF1b

1c. Orange Top Specimen ID: Stick CRF label here SCF1c

2. Purple Top: (check current status) SCF2
   - ❑ (1) Will not be collected →Q3
   - ❑ (2) Requested→Q3
   - ❑ (3) Collected → 2a. Date collected (dd/mmm/yyyy): __ __/ __ __ __/ __ __ __ __ SCF2a
   - ❑ (4) Shipped → 2b. Date Shipped (dd/mmm/yyyy): __ __/ __ __ __/ __ __ __ __ SCF2b

2c. Purple Top Specimen ID: Stick CRF label here SCF2c

Comments: SCF2c _____

_____

B. Study Specific Mucosal Biopsy Sample Collection

SCF3

3. Were any Rectal Biopsies Collected: ❑No →Q7 ❑ Yes → 3a. Date Collected (dd/mmm/yyyy): __ __/ __ __ __/ __ __ __ __ SCF3a

3b. If biopsy is performed during follow-up, have you re-collected consent: ❑(1)No→ICT ❑(2)Yes ❑(3)NA SCF3b

4. Biopsy for Histology
   a. ❑ (1) Will not be collected →Q5a ❑ (2) Collected SCF4a
   b. Collected as: ❑ (1) Formalin ❑ (2) Glass Slide SCF4b

4c. Histology Specimen ID Stick CRF label here SCF4c

5. RNA Later (3 Bx for genetic analysis)
   a. Biopsy #1: ❑ (1) Will not be collected ❑ (2) Collected ❑ (3) Shipped SCF5a
   b. Biopsy #2: ❑ (1) Will not be collected ❑ (2) Collected ❑ (3) Shipped SCF5b
   c. Biopsy #3: ❑ (1) Will not be collected ❑ (2) Collected ❑ (3) Shipped SCF5c

5d. RNA Specimen ID Stick CRF label here SCF5d

6. Biopsy Ship Date (dd/mmm/yyyy): __ __/ __ __ __/ __ __ __ __ SCF6

Comments: _____

_____

C. Study Specific Stool Sample Collection

7. Stool: (check current status): SCF7
   - ❑ (1) Will not be collected →END
   - ❑ (2) Requested → END
   - ❑ (3) Collected
   - ❑ (4) Shipped → Q7c

7d. Stool Specimen ID Stick CRF label here SCF7d

a. Frozen/On ice when received from family: ❑Yes ❑No ❑Unknown SCF7a

b. Date collected (Date passed from participant) (dd/mmm/yyyy): __ __/ __ __ __/ __ __ __ __ SCF7b

c. Date Shipped (dd/mmm/yyyy): __ __/ __ __ __/ __ __ __ __ SCF7c

Comments: _____

_____

Gender: M F

PROTECT
Predicting Response to Standardized Pediatric Colitis Therapy

Standard Medical Therapy Follow-up Form

ID NUMBER: | | | | | | | |

FORM CODE: SMF
VERSION: A 02/20/12

Contact Occasion | | SEQ # | |

Date of Contact/Form Completion: | | / | | | / | | | SMF0a

Staff Code: | | | SMF0b

A. Record of Oral 5-ASA and Steroid Therapies

1. **Mesalamine (Pentasa):** Receiving therapy at last review: ..... ❑ Yes→Q1b ❑ No SMF1
   a. Commenced since last review (including today)?..... ❑ Yes ❑ No →Q2 SMF1a
      1. Start Date (dd/mmm/yyyy): _ _ / _ _ _ / _ _ _ _ SMF1a1
      2. Daily Dose (mg): _____ SMF1a2
      3. Form: ❑Whole ❑Open SMF1a3
   b. Still Ongoing? ❑Yes → 1. Ongoing Daily Dose: SMF1b1 _____ mg →Q2
      SMF1b
      ❑No → 2. Stop Date (dd/mmm/yyyy): _ _ / _ _ _ / _ _ _ _ SMF1b3
   c. Reason this medication was stopped or had dose reduced:
      1. Not apply to this patient..... ❑ Yes ❑ N SMF1c1
      2. Ineffective ..... ❑ Yes ❑ N SMF1c2
      3. Suspected intolerance..... ❑ Yes ❑ N SMF1c3
      4. Suspected drug toxicity..... ❑ Yes ❑ N SMF1c4
      5. Subjects's choice ..... ❑ Yes ❑ N SMF1c5
      6. Other, please specify..... ❑ Yes ❑ N SMF1c6

2. **Oral/IV Steroid Therapy:** Receiving therapy at last review? ..... ❑ Yes→Q2b ❑ N SMF2
   a. Commenced (and possibly completed) since last review (including today)? ❑Y→new STR ❑No →Q3 SMF2a
   b. Still Ongoing? ❑Yes →Update current STR →Q3 SMF2b
      ❑No → 1. Stop Date (dd/mmm/yyyy): _ _ / _ _ _ / _ _ _ _ SMF2b1 →Finalize current STR

B. Record of Rectal 5-ASA and Steroid Therapies

3. **Rectal 5-ASA:** Receiving therapy at last review: ..... ❑ Yes→Q3b ❑ No SMF3
   a. Commenced since last review (including today)?: ..... ❑ Yes ❑ No →Q4 SMF3a
      i. Start Date (dd/mmm/yyyy): _ _ / _ _ _ / _ _ _ _ SMF3a1
   b. Still Ongoing? ❑Yes →Q4 SMF3b
      ❑No → 1. Stop Date (dd/mmm/yyyy): _ _ / _ _ _ / _ _ _ _ SMF3b1

4. **Rectal Steroids:** Receiving therapy at last review: ..... ❑ Yes→Q4b ❑ No SMF4
   a. Commenced since last review (including today)?: ..... ❑ Yes ❑ No →End SMF4a
      i. Start Date (dd/mmm/yyyy): _ _ / _ _ _ / _ _ _ _ SMF4a1
   b. Still Ongoing? ❑Yes →End SMF4b
      ❑No → 1. Stop Date (dd/mmm/yyyy): _ _ / _ _ _ / _ _ _ _ SMF4b1

Gender: M F

Standard Medical Therapy Follow-up Form

ID NUMBER: | | | | | | | |

FORM CODE: SMF
VERSION: B 6/20/2014

Contact Occasion | | |

Seq # | | |

Date of Contact: | | / | | | | / | SMF0a | | |

Staff Code: | | SMF0b | | |

FDF # SMF0c | | |

A. Record of Oral 5-ASA and Steroid Therapies

1.Mesalamine (Pentasa): On therapy at last review: ❑ Yes→Q1b ❑ No SMF1

(Note: Record non-Pentasa 5-ASAs on the AMT.)

a. Commenced since last review (including today)?..... ❑ Yes ❑ No →Q2 SMF1a

1. Start Date (dd/mmm/yyyy): _ _ / _ _ _ / _ _ _ _ SMF1a1
2. Daily Dose (mg): _____ SMF1a2
3. Form: ❑Whole→Q1d ❑Open →Q1d SMF1a3

SMF1b b. Still Ongoing? ❑ (1) Yes → 1. Ongoing Daily Dose: _____ mg →Q1d SMF1b1

❑ (2) Yes reduced → 2. Reduced Daily Dose: _____ mg →Q1c SMF1b2

❑ (3) No → 3. Stop Date (dd/mmm/yyyy): _ _ / _ _ _ / _ _ _ _ SMF1b3

c. Reason this medication was stopped or had dose reduced:

SMF1c1 1. Ineffective..... ❑ Yes ❑ No

SMF1c2 2. Suspected intolerance ..... ❑ Yes ❑ No

SMF1c3 3. Suspected drug toxicity ..... ❑ Yes ❑ No

4. Participant's choice..... ❑ Yes ❑ No SMF1c4

5. Other ..... ❑ Yes ❑ No→Q1d SMF1c5

5a. Specify:_____ SMF1c5a

d. Was any drug dispensed at this visit? ..... ❑ Yes ❑ No →Q1e SMF1d

1. How many pills were dispensed at this visit? _____ SMF1d1

e. Was any drug brought in during this visit?..... ❑ Yes ❑ No SMF1e

1. How many previously distributed pills does the participant still have? _____ SMF1e1

2. **Oral/IV Steroid Therapy:** Receiving therapy at last review? ..... ❑ Yes→Q2b ❑ No SMF2

a. Commenced (and possibly completed) since last review (including today)?... ❑Yes→new STR ❑No →Q3 SMF2a

b. Still Ongoing?..... ❑Yes →Update current STR →Q3 SMF2b

❑No → 1. Stop Date (dd/mmm/yyyy): _ _ / _ _ _ / _ _ _ _ →Finalize current STR SMF2b1

B. Record of Rectal 5-ASA and Steroid Therapies

3. **Rectal 5-ASA:** Receiving therapy at last review: ..... ❑ Yes→Q3b ❑ No SMF3

a. Commenced since last review (including today)?: ..... ❑ Yes ❑ No →Q4 SMF3a

1. Start Date (dd/mmm/yyyy): _ _ / _ _ _ / _ _ _ _ SMF3a1

b. Still Ongoing?..... ❑Yes →Q4 SMF3b

❑No → 1. Stop Date (dd/mmm/yyyy): _ _ / _ _ _ / _ _ _ _ SMF3b1

4. **Rectal Steroids:** Receiving therapy at last review: ..... ❑ Yes→Q4b ❑ No SMF4

a. Commenced since last review (including today)?: ..... ❑ Yes ❑ No →End SMF4a

1. Start Date (dd/mmm/yyyy): _ _ / _ _ _ / _ _ _ _ SMF4a1

b. Still Ongoing?..... ❑Yes →End SMF4b

❑No → 1. Stop Date (dd/mmm/yyyy): _ _ / _ _ _ / _ _ _ _ SMF4b1

Gender: M F

PROTECT
Predicting Response to Standardized Pediatric Colitis Therapy

Steroid Treatment Record Form

ID NUMBER: P | FORM CODE: STR | VERSION: A 02/17/12 | Contact Occasion | SEQ #

Date of Form Completion: __/__/__ STR0a | Staff Code: STR0b

Instruction: Complete a new form for every course of corticosteroids commenced, recording the dose adjustment until the therapy is ceased completely.

A. Record of Systemic Corticosteroid Therapy

1. **Name of Corticosteroid Agent (select one):** STR1

- ❑ (1) IV Methylprednisone
- ❑ (2) Oral Prednisone (Tablets)
- ❑ (3) Oral Prednisolone (Tablets)
- ❑ (4) IV Hydrocortisone
- ❑ (5) Oral Prednisone (Liquid)
- ❑ (6) Oral Prednisolone (Liquid)

Administration details:

	A. Date (dd/mmm/yyyy)	B. Dose (mg/day)
2.	__ __/ __ __ __/ __ __ __ __ STR2a	_____ STR2b
3.	__ __/ __ __ __/ __ __ __ __ STR3a	_____ STR3b
4.	__ __/ __ __ __/ __ __ __ __ STR4a	_____ STR4b
5.	__ __/ __ __ __/ __ __ __ __ STR5a	_____ STR5b
6.	__ __/ __ __ __/ __ __ __ __ STR6a	_____ STR6b
7.	__ __/ __ __ __/ __ __ __ __ STR7a	_____ STR7b
8.	__ __/ __ __ __/ __ __ __ __ STR8a	_____ STR8b
9.	__ __/ __ __ __/ __ __ __ __ STR9a	_____ STR9b
10.	__ __/ __ __ __/ __ __ __ __ STR10a	_____ STR10b
11.	__ __/ __ __ __/ __ __ __ __ STR11a	_____ STR11b
12.	__ __/ __ __ __/ __ __ __ __ STR12a	_____ STR12b
13.	__ __/ __ __ __/ __ __ __ __ STR13a	_____ STR13b
14.	__ __/ __ __ __/ __ __ __ __ STR14a	_____ STR14b
15.	__ __/ __ __ __/ __ __ __ __ STR15a	_____ STR15b
16.	__ __/ __ __ __/ __ __ __ __ STR16a	_____ STR16b
17.	__ __/ __ __ __/ __ __ __ __ STR17a	_____ STR17b
18.	__ __/ __ __ __/ __ __ __ __ STR18a	_____ STR18b
19.	__ __/ __ __ __/ __ __ __ __ STR19a	_____ STR19b
20.	__ __/ __ __ __/ __ __ __ __ STR20a	_____ STR20b
21.	__ __/ __ __ __/ __ __ __ __ STR21a	_____ STR21b
22.	__ __/ __ __ __/ __ __ __ __ STR22a	_____ STR22b
23.	__ __/ __ __ __/ __ __ __ __ STR23a	_____ STR23b
24.	__ __/ __ __ __/ __ __ __ __ STR24a	_____ STR24b
25.	__ __/ __ __ __/ __ __ __ __ STR25a	_____ STR25b

26. **Final Disposition:**

a. Date of last dose (dd/mmm/yyyy): __ __/ __ __ __/ __ __ __ __ STR26a

b. Final Outcome (select one): STR26b

- ❑ (1) Ceased, no further steroids
- ❑ (2) Converted to Oral
- ❑ (3) Converted to IV
- ❑ (4) Continued, see subsequent STR
- ❑ (5) Ceased, failed→ AMT

PROTECT

Gender: M F

Steroid Treatment Record Form

ID NUMBER: ☐☐☐☐☐☐☐☐ FORM CODE: STR VERSION: B 07/08/13 Contact Occasion ☐☐ Seq # ☐☐

Date of Form Completion: ☐☐/☐☐/☐☐☐☐ SCF0a Staff Code: ☐☐☐ SCF0b FDF # ☐☐ SCF0c

A. Record of Systemic Corticosteroid Therapy

1. Name of Corticosteroid Agent (select one): STR1

❑ (1) IV Methylprednisolone ❑ (4) IV Hydrocortisone ❑ (7) Budesonide MMX
❑ (2) Oral Prednisone (Tablets) ❑ (5) Oral Prednisone (Liquid) ❑ (8) Systemic Corticosteroids for non IBD indications
❑ (3) Oral Prednisolone (Tablets) ❑ (6) Oral Prednisolone (Liquid)

Administration details:

	A. Date (dd/mmm/yyyy)	B. Dose (mg/day)	C. Ongoing? Yes	No
2. STR2a	__ __/ __ __ __/ __ __ __ __	STR2b _____	❑	❑→Q26 STR2c
3. STR3a	__ __/ __ __ __/ __ __ __ __	STR3b _____	❑	❑→Q26 STR3c
4. STR4a	__ __/ __ __ __/ __ __ __ __	STR4b _____	❑	❑→Q26 STR4c
5. STR5a	__ __/ __ __ __/ __ __ __ __	STR5b _____	❑	❑→Q26 STR5c
6. STR6a	__ __/ __ __ __/ __ __ __ __	STR6b _____	❑	❑→Q26 STR6c
7. STR7a	__ __/ __ __ __/ __ __ __ __	STR7b _____	❑	❑→Q26 STR7c
8. STR8a	__ __/ __ __ __/ __ __ __ __	STR8b _____	❑	❑→Q26 STR8c
9. STR9a	__ __/ __ __ __/ __ __ __ __	STR9b _____	❑	❑→Q26 STR9c
10. STR10a	__ __/ __ __ __/ __ __ __ __	STR10b _____	❑	❑→Q26 STR10c
11. STR11a	__ __/ __ __ __/ __ __ __ __	STR11b _____	❑	❑→Q26 STR11c
12. STR12a	__ __/ __ __ __/ __ __ __ __	STR12b _____	❑	❑→Q26 STR12c
13. STR13a	__ __/ __ __ __/ __ __ __ __	STR13b _____	❑	❑→Q26 STR13c
14. STR14a	__ __/ __ __ __/ __ __ __ __	STR14b _____	❑	❑→Q26 STR14c
15. STR15a	__ __/ __ __ __/ __ __ __ __	STR15b _____	❑	❑→Q26 STR15c
16. STR16a	__ __/ __ __ __/ __ __ __ __	STR16b _____	❑	❑→Q26 STR16c
17. STR17a	__ __/ __ __ __/ __ __ __ __	STR17b _____	❑	❑→Q26 STR17c
18. STR18a	__ __/ __ __ __/ __ __ __ __	STR18b _____	❑	❑→Q26 STR18c
19. STR19a	__ __/ __ __ __/ __ __ __ __	STR19b _____	❑	❑→Q26 STR19c
20. STR20a	__ __/ __ __ __/ __ __ __ __	STR20b _____	❑	❑→Q26 STR20c
21. STR21a	__ __/ __ __ __/ __ __ __ __	STR21b _____	❑	❑→Q26 STR21c
22. STR22a	__ __/ __ __ __/ __ __ __ __	STR22b _____	❑	❑→Q26 STR22c
23. STR23a	__ __/ __ __ __/ __ __ __ __	STR23b _____	❑	❑→Q26 STR22c
24. STR24a	__ __/ __ __ __/ __ __ __ __	STR24b _____	❑	❑→Q26 STR24c
25. STR25a	__ __/ __ __ __/ __ __ __ __	STR25b _____	❑	❑→Q26 STR25c

26. Final Disposition:

a. Final Outcome (select one): STR26a

❑ (1) Ceased, no further steroids ❑ (3) Converted to IV ❑ (5) Ceased, failed→AMT
❑ (2) Converted to Oral ❑ (4) Continued, see subsequent STR→End

b. Date of last dose (dd/mmm/yyyy): __ __/ __ __ __/ __ __ __ __ STR26b

Gender: M F

PROTECT
Predicting Response to Standardized Pediatric Colitis Therapy

Study Treatment at Day Zero

ID NUMBER: ☐☐☐☐☐☐☐☐ FORM CODE: STZ VERSION: A 02/20/12 Contact Occasion ☐☐ SEQ # ☐☐

Date of Form Completion: ☐☐/☐☐/☐☐☐☐ STZ0a Staff Code: STZ0b ☐

Please indicate which listed medications were received on Day 0 (treatment initiation) and record start date and daily dose:

Category / Name	A. Received (Yes / No)	B. Start Date (dd/mmm/.yyyy)	C. Total Daily Dose (mg)
5-ASA	STZ1a	STZ1b	STZ1c
1. Mesalamine (Pentasa) complete capsule	❑ ❑	__ __/__ __ __/__ __ __ __	_____
2. Mesalamine (Pentasa) opened capsule	STZ2a ❑ ❑	STZ2b __ __/__ __ __/__ __ __ __	STZ2c _____
3. Rectal 5-ASA suppository	❑ STZ3a ❑	STZ3b __ __/__ __ __/__ __ __ __	
4. Rectal 5-ASA enema	❑ STZ4a ❑	STZ4b __ __/__ __ __/__ __ __ __	
Corticosteroids		__ __/__ __ __/__ __ __ __	
5. Prednisone or Prednisolone	❑→STR ❑ STZ5a		
6. Rectal Steroid suppository	❑ STX6a ❑	STZ6b __ __/__ __ __/__ __ __ __	
7. Rectal Steroid suppository	❑ STZ7a ❑	STZ7b __ __/__ __ __/__ __ __ __	

8. Was the subject admitted to the hospital at the commencement of therapy? ..... ❑Y →HDF ❑N→End STZ8

9. Did the subject receive IV Steroid therapy?..... ❑Y→STR ❑N→Q11 STZ9

10. Was IV steroid therapy changed to oral therapy within 7 days? .....❑Yes →Eligible for standardized therapy protocol STZ10
❑No*

11. Did the subject undergo Colectomy during this admission? ❑Y→CLF ❑N STZ11

12. Did the subject receive rescue medical therapy?.....❑Y*→AMT ❑N→Q17 STZ12

Category	A. Received (Yes / No)	B. Start Date (dd/mmm/.yyyy)	C. Initial Dose (mg)
Calcineurin Inhibitors	STZ13a	STZ13b	STZ13c
13. Tacrolimus	❑ ❑	__ __/__ __ __/__ __ __ __	_____
14. Cyclosporin	STZ14a ❑ ❑	STZ14b __ __/__ __ __/__ __ __ __	STZ14c ___ ___ ___
Biologic Agents	STZ15a	STZ15b	STZ15c
15. Infliximab	❑ ❑	__ __/__ __ __/__ __ __ __	___ ___ ___ ___
16. Adalimumab	STZ16a ❑ ❑	__ __/__ __ __/__ __ __ __	___ ___ ___ ___
	STZ16a	STZ16a	STZ16a

17. Did the subject receive a second line medical agent? ..... ❑Y*→AMT ❑N→End STZ17

18. Azathioprine	STZ18a ❑ ❑	__ __/__ __ __/__ __ __ __	STZ18c ___ ___ ___
19. 6-Mercaptopurine	STZ19a ❑ ❑	__ __/__ __ __/__ __ __ __	STZ19c ___ ___ ___
20. Methotrexate (SC/IM)	STZ20a ❑ ❑	__ __/__ __ __/__ __ __ __	STZ20c ___ ___ ___
21. Methotrexate (Oral)	STZ121a ❑ ❑	__ __/__ __ __/__ __ __ __	STZ21c ___ ___ ___

22. Have any specific lab tests been performed related to the above medications:..... ❑Y→ALT ❑N STZ22

The Subject will NOT be required to follow the standardized therapy protocol, however will continue to be reviewed according to the protocol for the duration of the study.

Gender: M F

Study Treatment Day Zero Form

ID NUMBER: | | | | | | | |

FORM CODE: STZ
VERSION: B 03/26/2013

Contact Occasion | |

SEQ # | |

Date of Contact: | | / | | | / | | | | | STZ0a

STZ0b Staff Code: | | |

Please indicate which listed medications were commenced on Day 0 (treatment initiation) and record start date and daily dose:

Category	Name	A Commenced Yes	A Commenced No	B Start Date (dd/mmm/.yyyy)	C Total Daily Dose (mg)
5-ASA					
1.	Mesalamine (Pentasa) complete capsule	❑ STZ1a	❑	__ __/ __ __ __/__ __ __ __ STZ1b	_____ STZ1c
2.	Mesalamine (Pentasa) opened capsule	❑ STZ2a	❑	__ __/ __ __ __/__ __ __ __ STZ2b	_____ STZ2c
3.	If yes (Q1a or Q2a), how many pills were dispensed at this visit? _____ STZ3				
4.	Rectal 5-ASA	❑ STZ4a	❑	__ __/ __ __ __/__ __ __ __ STZ4b	
Corticosteroids					
5.	Oral Prednisone or Prednisolone	❑→STR	❑ STZ5		
6.	Rectal Steroid suppository	❑	❑	__ __/ __ __ __/__ __ __ __ STZ6	

7. Was the participant in the hospital at the commencement of therapy? ..... ❑Y→HDF ❑N→End STZ7

8. Did the participant receive IV Steroid therapy? ..... ❑Y→STR ❑N→Q10 STZ8

9. Was IV steroid therapy changed to oral therapy within 14 days? ..... ❑Y→Eligible for standardized therapy protocol, STR
❑N* STZ9

10. Did the participant undergo Colectomy during this admission? ..... ❑Y*→CLF ❑N STZ10

11. Did the participant receive calcineurin inhibitor therapy? ..... ❑Y ❑N→Q12 STZ11
    a. Tacrolimus: ..... ❑Y→AMT ❑N STZ11a
    b. Cyclosporin: ..... ❑Y→AMT ❑N STZ11b

12. Did the participant receive biologic therapy? ..... ❑Y ❑N→Q13 STZ12
    a. Infliximab ..... ❑Y→AMT ❑N STZ12a
    b. Adalimumab ..... ❑Y→AMT ❑N STZ12b

13. Did the participant receive immunomodulator therapy? ..... ❑Y ❑N→Q14 STZ13
    a. Azathioprine ..... ❑Y→AMT ❑N STZ13a
    b. 6-Mercaptopurine ..... ❑Y→AMT ❑N STZ13b
    c. Methotrexate (SC/IM) ..... ❑Y→AMT ❑N STZ13c
    d. Methotrexate (Oral) ..... ❑Y→AMT ❑N STZ13d

14. Have any specific lab tests been performed related to the above medications: ❑Y→ALF ❑N STZ14

The Participant will NOT be required to follow the standardized therapy protocol, however will continue to be reviewed according to the protocol for the duration of the study.

Gender: M F

Study Withdrawal Form

ID NUMBER: | | | | | | | |

FORM CODE: SWF
VERSION: A 06/18/12

Contact Occasion | | |

Seq # | | |

Date of Form Completion: | | / | | | | / | | SWF0a | | |

Staff Code: | | | SWF0b

FDF # | | SWF0c

1. Date of study withdrawal : ____ ____ /____ ____ ____/ ____ ____ ____ ____ SWF1
   dd mmm yyyy

2. Indicate the reason for withdrawal from the study: (Choose one) SWF2
   - Participant no longer wishes to participate ..... ❑(1)
   - Participant lost-to-follow-up ..... ❑ (2)
   - Study treatment was never started ..... ❑ (3)
   - Participant was diagnosed with Crohn's disease ..... ❑ (4)
   - Participant does not meet other eligibility requirements ..... ❑ (5)
   - Principal Investigator elected to withdraw participant ..... ❑ (6)
   - Other ..... ❑ (7)

   2a. Please specify: _____ SWF2a

3. What is the disposition of the participant's specimens and data? (Choose one) SWF3
   - Allow use of previously collected data and/or specimens ..... ❑ (1)
   - Withdraw all their data from study databases ..... ❑ (2)
   - Request that any stored samples be destroyed ..... ❑ (3)
   - Withdraw data and request specimens be destroyed ..... ❑ (4)
   - Unable to ascertain due to participant unreachable ..... ❑ (5)
   - Other ..... ❑ (6)

   3a. If other, please specify: _____ SWF3a

4. If there was a change in disposition of participant's specimens and data, what is the effective date of this change? ____ ____ /____ ____ ____/ ____ ____ ____ ____ SWF4
   dd mmm yyyy

5. Which staff member(s) at the site discussed withdrawal with this participant ?
   - a. Study Coordinator ..... ❑ Y ❑ N SWF5a
   - b. Principal Investigator ..... ❑ Y ❑ N SWF5b
   - c. Study staff ..... ❑ Y ❑ N SWF5c
   - d. Other ..... ❑ Y ❑ N SWF5d

   5d1. If other, please specify: _____ SWF5d1

Gender: M F

Study Withdrawal Form

ID NUMBER: | | | | | | | |

FORM CODE: SWF
VERSION: B 11/13/12

Contact Occasion | | |

Seq # | | |

Date of Form Completion: | | / | | | | / | | | SWF0a

Staff Code: | | | SWF0b

FDF # | | SWF0c

1. Date of study withdrawal : ____ ____ /____ ____ ____/ ____ ____ ____ ____ SWF1
   dd mmm yyyy

2. Indicate the reason for withdrawal from the study: (Choose one) SWF2
   - Participant no longer wishes to participate ..... ❑ (1))
   - Participant lost-to-follow-up ..... ❑ (2)
   - Participant was diagnosed with Crohn's disease ..... ❑ (3)
   - Principal Investigator elected to withdraw participant ..... ❑ (4)
   - Other ..... ❑ (5)

   2a. Please specify: _____ SWF2a

3. What is the disposition of the participant's specimens and data? (Choose one) SWF3
   - Allow use of previously collected data and/or specimens ..... ❑ (1)
   - Withdraw all their data from study databases ..... ❑ (2)
   - Request that any stored samples be destroyed ..... ❑ (3)
   - Withdraw data and request specimens be destroyed ..... ❑ (4)
   - Unable to ascertain due to participant unreachable ..... ❑ (5)
   - Other ..... ❑ (6)

   3a. If other, please specify: _____ SWF3a

4. If there was a change in disposition of participant's specimens and data, what is the effective date of this change? ____ ____ /____ ____ ____/ ____ ____ ____ ____ SWF4
   dd mmm yyyy

5. Which staff member(s) at the site discussed withdrawal with this participant ?
   - a. Study Coordinator ..... ❑ Y ❑ N SWF5a
   - b. Principal Investigator ..... ❑ Y ❑ N SWF5b
   - c. Study staff ..... ❑ Y ❑ N SWF5c
   - d. Other ..... ❑ Y ❑ N SWF5d

   5d1. If other, please specify: _____ SWF5d1

Gender: M F

Study Withdrawal Form

ID NUMBER: | | | | | | | |

FORM CODE: SWF
VERSION: D 12/15/2015

Contact Occasion | | |

Seq # | | |

Date of Form Completion: | | / | | | | / | | SWF0a | | |

Staff Code: | | SWF0b | |

FDF # | | SWF0c

1. Date of study withdrawal/completion : ____ ____ /____ ____ ____/ ____ ____ ____ ____ SWF1
   dd mmm yyyy

2. Indicate the reason for withdrawal from the study: (Choose one) SWF2
   - Participant no longer wishes to participate ..... ❑ (1)
   - Participant lost-to-follow-up ..... ❑ (2)
   - Participant was diagnosed with Crohn's disease ..... ❑ (3)
   - Principal Investigator elected to withdraw participant ..... ❑ (4)
   - Other ..... ❑ (5)
     - 2a. Please specify: _____ SWF2a
   - Participant completed study ..... ❑ (6) → Q5

3. What is the disposition of the participant's specimens and data? (Choose one) SWF3
   - Allow use of previously collected data and/or specimens ..... ❑ (1)
   - Withdraw all their data from study databases ..... ❑ (2)
   - Request that any stored samples be destroyed ..... ❑ (3)
   - Withdraw data and request specimens be destroyed ..... ❑ (4)
   - Unable to ascertain due to participant unreachable ..... ❑ (5)
   - Other ..... ❑ (6)
     - 3a. If other, please specify: _____ SWF3a

4. If there was a change in disposition of participant's specimens and data, what is the effective date of this change? ____ ____ /____ ____ ____/ ____ ____ ____ ____ SWF4
   dd mmm yyyy

5. Which staff member(s) at the site discussed withdrawal/completion with this participant? SWF5
   - a. Study Coordinator ..... ❑ Y ❑ N
   - b. Principal Investigator ..... ❑ Y ❑ N
   - c. Study staff ..... ❑ Y ❑ N
   - d. Other ..... ❑ Y ❑ N
     - 5d1. If other, please specify: _____

6. Please evaluate the participant's compliance with their Pentasa regimen during Year 1. This should be the investigator or coordinator's assessment rather than an assessment provided by the participant. SWF6
   - a. Good (i.e. Pentasa taken as directed most of the time, 80-100% compliant)..... ❑ (1)
   - b. Fair (i.e. Pentasa taken as directed some of the time, 50-80% compliant)..... ❑ (2)
   - c. Poor (i.e. Pentasa frequently not taken as directed, <50% compliant)..... ❑ (3)
   - d. Not applicable (Pentasa not taken during year 1)..... ❑ (4)

7. Please indicate the status for this participant at withdrawal/completion. Did the participant:
   - a. Ever have a colectomy ❑Y ❑N SWF7a
   - b. Ever take UC rescue medication (azathioprine, 6-MP, methotrexate, tacrolimus, cyclosporine, infliximab, adalimumab, other newly available biologics) ..... ❑Y ❑N SWF7b