Paed-Intestinal Disease Collaboration Projects: Local Registration Record

1. Participant Registration for the Paed-Intestinal Disease Collaboration Projects

Participant Study Registration Number:
*(Affix your Subject ID barcode sticker OR handwrite your **Subject ID here**.*
SUBJECT ID MUST BE ON ALL PAGES.)

Participant First Name: _____ **Participant Family Name:** _____

Local Hospital Medical Record Number: _____ **Local Site Identifier:** _____

Date of Birth: ____ ____ /____ ____ ____/ ____ ____ ____ ____ **Gender:** *Male* *Female*
dd **mmm** **yyyy**

This information is NOT to be forwarded to the Central Data Coordinating Centre

DO NOT FAX THIS PAGE

Please file this information securely and separate from other study-related data

Paed-Intestinal Disease Collaboration Projects: Local Registration Record

2. Participant Registration Details for Paed-Intestinal Disease Collaboration Projects

Participant Study Registration Number:
*(Affix your Subject ID barcode sticker OR handwrite your **Subject ID here**.*
SUBJECT ID MUST BE ON ALL PAGES.)

Year of Birth: ____ ____ ____ ____ **Gender:** *Male* *Female*

3. Study Consent Procedures

3.1 Was consent obtained ❑Yes ❑No

3.2 Date consent was obtained ____ ____ /____ ____ ____/ ____ ____ ____ ____
dd **mmm** **yyyy**

3.3 Consent Title ____

3.4 Consent Version Date ____ ____ /____ ____ ____/ ____ ____ ____ ____
dd **mmm** **yyyy**

3.5 Signee:
❑Participant ❑Mother ❑Father ❑Both Parents ❑Legal Guardian ❑Other

3.6 Was assent obtained ❑Yes ❑No

3.7 Date assent was obtained ____ ____ /____ ____ ____/ ____ ____ ____ ____
dd **mmm** **yyyy**

3.8 Assent Version Date ____ ____ /____ ____ ____/ ____ ____ ____ ____
dd **mmm** **yyyy**

4 Confirmation of Enrollment Registration on Database

4.1 **Record of the System Generated Paed-Intestinal Disease Collaboration Project Unique Enrollment Number:**
(NB: This number will be provided to you by the Central Data Coordinating Centre)

NatIdPID: ❑❑❑❑❑❑❑

(This is NOT the Participant Registration Barcode Number, but a unique number that will be provided by the DCC following registration of the participant's enrollment on the database)

Comments from Registration Process

Paed-Intestinal Disease Collaboration Projects: Details Confirming Diagnosis

Participant Study Registration Number: **Gender:** *Male* *Female*

*(Affix your Subject ID barcode sticker OR handwrite your **Subject ID here**.*
SUBJECT ID MUST BE ON ALL PAGES.)

5. Does the Participant meet the study's diagnostic definition of Intestinal Disease?

6.1 Indicate which of the following features are, or were previously, apparent in this participant regarding the diagnosis of Intestinal Disease

Y = Yes N = No U = Unknown

5.1.1) History of the following:

	Y	N	U		Y	N	U		Y	N	U
Diarrhea	❑	❑	❑	*Abdominal Pain*	❑	❑	❑	*Weight Loss*	❑	❑	❑
Rectal Bleeding	❑	❑	❑	*Malaise*	❑	❑	❑	*Linear Growth Failure*	❑	❑	❑

5.1.2) Endoscopic Findings (includes capsule endoscopy):

❑ Not available at enrollment ❑ Not available by first follow-up

	Y	N	U		Y	N	U
Discontinuous Ulcerations	❑	❑	❑	*Cobblestoning*	❑	❑	❑

5.1.3) Radiological Findings:

❑ Not available at enrollment ❑ Not available by first follow-up

	Y	N	U
Cobblestoning or ulceration of the mucosa	❑	❑	❑

5.1.4) Laparotomy Findings: ❑ Not applicable

	Y	N	U		Y	N	U
Typical bowel wall induration	❑	❑	❑	*Mesenteric lymphadenopathy*	❑	❑	❑
Serosa with creeping fat or other inflammatory changes	❑	❑	❑				

5.1.5) Histopathological Findings:

❑ Not available at enrollment ❑ Not available by first follow-up

	Y	N	U
Patchy inflammatory cell infiltrates	❑	❑	❑
Epithelial granuloma in the absence of identifiable infectious agents	❑	❑	❑

Comments:

Paed-Intestinal Disease Collaboration Projects: Demographics and History (1)

Participant Study Registration Number: **Gender:** *Male* *Female*

*(Affix your Subject ID barcode sticker OR handwrite your **Subject ID here**.*
SUBJECT ID MUST BE ON ALL PAGES.)

6. Participant's Ethnic Demographics

6.1 Participant's country of birth: _____ *6.2* Estimated date of arrival in present country : ❑N/A _____

7 Family's Ethnic Demographics (in relation to the Proband)

		Stated Jewish Background					*Stated Hispanic Background*		
	Stated Racial Background (textual)	N	J	NA	JA	U	H	NH	U
Maternal grandmother	_____	❑	❑	❑	❑	❑	❑	❑	❑
Maternal grandfather	_____	❑	❑	❑	❑	❑	❑	❑	❑
Paternal grandmother	_____	❑	❑	❑	❑	❑	❑	❑	❑
Paternal grandfather	_____	❑	❑	❑	❑	❑	❑	❑	❑

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

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

8. Participant's Birth History

Mode of delivery:

8.1 Was the participant delivered by caesarean section? ❑Yes ❑No ❑Unknown

Participant's milk source as an infant:

8.2 Was the participant ever Breast Fed? ❑Yes ❑No ❑Unknown

If 'yes':

8.2.1 Approximate Duration of ***Exclusive*** Breastfeeding: ❑ never ❑ <1month ❑ 1-3 months ❑3-6 months ❑ >6 months

9. Participant Environmental and Medical History

Cigarette Smoke Exposure:

9.1.1 Was the participant a current smoker around the time of Dx? ❑Yes ❑No ❑Unknown

9.1.2 Did the participant live at home with a smoker anytime during the 6 month period prior to Dx? ❑Yes ❑No ❑Unknown

9.1.3 Did the participant live at home with a smoker at anytime, more than 6 months prior to Dx? ❑Yes ❑No ❑Unknown

9.1.4 Did the participant's biological mother smoke during pregnancy? ❑Yes ❑No ❑Unknown

Specific Medical History Details:

9.2.1 Has the participant had recurrent/persistent folliculitis? ❑Yes ❑No ❑Unknown

9.2.2 Does the participant have documented cows' milk protein allergy? ❑Yes ❑No ❑Unknown

Comments:

Paed-Intestinal Disease Collaboration Projects: Demographics and History (2)

Participant Study Registration Number: **Gender:** *Male* *Female*

*(Affix your Subject ID barcode sticker OR handwrite your **Subject ID here**.*
SUBJECT ID MUST BE ON ALL PAGES.)

10. Summary of Familial History of IBD

Does any member of the participant's family have a known history of IBD:

Full Sibling

Ulcerative Colitis	❑Y	❑N	❑U	❑NA	*IBD-U*	❑Y	❑N	❑U	❑NA
Crohn Disease	❑Y	❑N	❑U	❑NA	*Confirmed IBD (unaware of type)*	❑Y	❑N	❑U	❑NA

Y= Yes, N= No, U=Unknown, NA=Not Applicable (no full Siblings)

	Unknown	*No Hx of IBD*	*Ulcerative Colitis*	*Crohn Disease*	*IBD-U*	*Confirmed IBD (unaware of type)*
Mother	❑	❑	❑	❑	❑	❑
Father	❑	❑	❑	❑	❑	❑

11. Summary of Personal and Family History

Does the participant, or any member of the family, have a known history of any of the following:

	Participant			**Full Sibling**				**Mother**			**Father**		
Atopy or Asthma	❑Y	❑N	❑U	❑Y	❑N	❑U	❑NA	❑Y	❑N	❑U	❑Y	❑N	❑U
Multiple Sclerosis	❑Y	❑N	❑U	❑Y	❑N	❑U	❑NA	❑Y	❑N	❑U	❑Y	❑N	❑U
IDDM	❑Y	❑N	❑U	❑Y	❑N	❑U	❑NA	❑Y	❑N	❑U	❑Y	❑N	❑U
Rheumatoid Arthritis	❑Y	❑N	❑U	❑Y	❑N	❑U	❑NA	❑Y	❑N	❑U	❑Y	❑N	❑U
Lupus	❑Y	❑N	❑U	❑Y	❑N	❑U	❑NA	❑Y	❑N	❑U	❑Y	❑N	❑U
Psoriasis	❑Y	❑N	❑U	❑Y	❑N	❑U	❑NA	❑Y	❑N	❑U	❑Y	❑N	❑U
Ankylosing Spondylitis				❑Y	❑N	❑U	❑NA	❑Y	❑N	❑U	❑Y	❑N	❑U
Autoimmune Thyroid Disease	❑Y	❑N	❑U	❑Y	❑N	❑U	❑NA	❑Y	❑N	❑U	❑Y	❑N	❑U
Celiac Disease (Bx proven)	❑Y	❑N	❑U	❑Y	❑N	❑U	❑NA	❑Y	❑N	❑U	❑Y	❑N	❑U

Y= Yes, N= No, U=Unknown, NA=Not Applicable (no full Siblings)

12. Summary of Extra Intestinal Manifestations observed in this Participant

	Recognized				Approx Date first Recognized	Comments
	Unknown	*Never*	*PreDx*	*AroundDx*		
Small Joint Arthritis	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (*dd* / *mmm* / *yyyy*)	_____
Large Joint Arthritis	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (*dd* / *mmm* / *yyyy*)	_____
Ankylosing Spondylitis	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (*dd* / *mmm* / *yyyy*)	_____
Sacro-Ileitis	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (*dd* / *mmm* / *yyyy*)	_____
Erythema Nodosum	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (*dd* / *mmm* / *yyyy*)	_____
Pyoderma Gangrenosum	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (*dd* / *mmm* / *yyyy*)	_____
Iritis/Uveitis	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (*dd* / *mmm* / *yyyy*)	_____
Autoimmune Hepatitis	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (*dd* / *mmm* / *yyyy*)	_____
Primary Sclerosing Cholangitis	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (*dd* / *mmm* / *yyyy*)	_____
Pancreatitis	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (*dd* / *mmm* / *yyyy*)	_____

Comments:

Paed-Intestinal Disease Collaboration Projects: Clinical Data at Diagnosis

Participant Study Registration Number: **Gender:** *Male* *Female*

*(Affix your Subject ID barcode sticker OR handwrite your **Subject ID here**.*
SUBJECT ID MUST BE ON ALL PAGES.)

14. Clinical Information at Diagnosis

14.1 Date of Diagnosis ____ ____ / ____ ____ ____ / ____ ____ ____ ____ **14.1a Age at Diagnosis**____ ____, ____ ____

dd **mmm** **yyyy** **yrs** **mths**

14.2 Diagnostic Impression at Diagnosis: ❑ CD ❑ UC ❑ IBD-U ❑ Not IBD

15. Historical Anthropometric Data

Parent Height:

Biological Mother: _____ cm
(Data unobtainable ❑)

Biological Father: _____ cm
(Data unobtainable ❑)

Participant's Growth Prior to Dx (if available):
(Data unobtainable ❑)

Date *(dd / mmm / yyyy)*	Height (cm)	Weight (kg)
__ __ / __ __ __ / __ __ __ __		
__ __ / __ __ __ / __ __ __ __		
__ __ / __ __ __ / __ __ __ __		
__ __ / __ __ __ / __ __ __ __		
__ __ / __ __ __ / __ __ __ __		
__ __ / __ __ __ / __ __ __ __		
__ __ / __ __ __ / __ __ __ __		
__ __ / __ __ __ / __ __ __ __		
__ __ / __ __ __ / __ __ __ __		
__ __ / __ __ __ / __ __ __ __		

16. Participant Anthropometry at Diagnosis

16.1 Anthropometrics:

Height (cm): _____ ❑ Clinic ❑ Self-reported Weight (kg):_____ ❑ Clinic ❑ Self-reported

Date these measurements were taken ____ ____ /____ ____ ____/ ____ ____ ____ ____
dd **mmm** **yyyy**

16.2 Tanner Stage:

❑ Physician assessed ❑ Self-reported ❑ Not assessed Breasts: 1 2 3 4 5 na Pubic Hair: 1 2 3 4 5 Genitalia: 1 2 3 4 5

16.2.1 Is the Participant Post-Menarchal? ❑Not Applicable ❑Yes ❑No ❑Unknown

Estimated Date of Menarche ____ ____ /____ ____ ____/ ____ ____ ____ ____
dd **mmm** **yyyy**

Paed-Intestinal Disease Collaboration Projects: Location & Behaviour Data at Diagnosis

Participant Study Registration Number: **Gender:** *Male* *Female*

*(Affix your Subject ID barcode sticker OR handwrite your **Subject ID here**.*
SUBJECT ID MUST BE ON ALL PAGES.)

19. Imaging Summary around the time of Diagnosis

	NP	P		NP	P
Upper Endoscopy	❑	❑	Capsule Endoscopy	❑	❑
Lower Endoscopy (Colon)	❑	❑	Lower Endoscopy (TI)	❑	❑
UGI Series/Followthrough	❑	❑	Ba Enema	❑	❑
Abdo Ultrasound	❑	❑	Abdo CT	❑	❑
Abdo MRI	❑	❑	WCC Labeled Scan	❑	❑

NP = not performed *P= performed*

20. Summary of Known Disease Location around the time of Diagnosis

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

	N	Mac	Mic	NA	U		N	Mac	Mic	NA	U
Oral	❑	❑	❑	❑	❑	Cecum	❑	❑	❑	❑	❑
Esophagus	❑	❑	❑	❑	❑	Asc Colon	❑	❑	❑	❑	❑
Stomach	❑	❑	❑	❑	❑	Trans Colon	❑	❑	❑	❑	❑
Duodenum	❑	❑	❑	❑	❑	Desc Colon	❑	❑	❑	❑	❑
Jej/Prox Ileum	❑	❑	❑	❑	❑	Sigmoid	❑	❑	❑	❑	❑
Distal Il/TI	❑	❑	❑	❑	❑	Rectum	❑	❑	❑	❑	❑

N= Normal *Mac = Macroscopic disease* *Mic = Microscopic Disease only* *NA = Not Assessed* *U = Unknown*

Comments:

21. Luminal Disease Behaviour at Diagnosis

	Yes	No	Unknown	
Stricturing/Fibrostenotic	❑	❑	❑	
If Yes, features:	❑	❑		Constant luminal narrowing on DI, endo or surgery
	❑	❑		Pre-stenotic Dilatation
	❑	❑		Obstructive signs/symptoms
	Yes	No	Unknown	
Internally Penetrating	❑	❑	❑	
If Yes, features:	❑	❑		Entero-enteric or entero-vesicular fistula/e
	❑	❑		Entero-cutaneous fistula/e
	❑	❑		Intra-abdominal abscess/es
	❑	❑		Intestinal Perforation

22. Presence of Perianal Disease around the time of Diagnosis

	Yes	No	Unknown
Large Skin Tags	❑	❑	❑
Ulcers	❑	❑	❑
Fissure/s	❑	❑	❑
Isolated Abscess	❑	❑	❑
Multiple Abscesses	❑	❑	❑
Perianal Fistula/e	❑	❑	❑
Recto-vaginal Fistula/e	❑	❑	❑
Ano-vaginal Fistula/e	❑	❑	❑

Paed-Intestinal Disease Collaboration Projects: Treatment Data at Diagnosis

Participant Study Registration Number: **Gender:** *Male* *Female*

*(Affix your Subject ID barcode sticker OR handwrite your **Subject ID here**.*
SUBJECT ID MUST BE ON ALL PAGES.)

24. Treatment around the time of Diagnosis

Please indicate which of the following medications were received and record the specified information

Category	Name	Received		Start Date (dd/mmm/.yyyy)	Initial Daily Dose (mg)
		No	*Yes*		
Supplements etc					
	Probiotic Supplement	❑	❑	_____	
	Omega-3 Supplement	❑	❑	_____	
Oral 5-ASA					
	Sulfasalazine	❑	❑	_____	_____
	Mesalazine	❑	❑	_____	_____
	Olsalazine	❑	❑	_____	_____
Antibiotics					
	Metronidazole (Flagyl)	❑	❑	_____	_____
	Ciprofloxacin	❑	❑	_____	_____
	Rifaxamin (Xifaxin)	❑	❑	_____	_____
Corticosteroids					
	MethylPrednisone	❑	❑	_____	_____
	Hydrocortisone IV	❑	❑	_____	_____
	Prednisone or Prednisolone	❑	❑	_____	_____
	Oral Budesonide	❑	❑	_____	_____
Immunomodulators					
	Azathioprine	❑	❑	_____	_____
	6-Mercaptopurine	❑	❑	_____	_____
	Tacrolimus	❑	❑	_____	_____
	Cyclosporin	❑	❑	_____	_____
				Date of First Dose (dd/mmm/.yyyy)	**Initial Dose** (mg)
	Methotrexate (SC/IM)	❑	❑	_____	_____
	Methotrexate (Oral)	❑	❑	_____	_____
Biologic Agents					
	Adalimumab	❑	❑	_____	_____
	Certolizumab	❑	❑	_____	_____
	Infliximab	❑	❑	_____	_____
	Natalizumab	❑	❑	_____	_____

Enteral Therapy					Est Cal/Day (Cal)	Exclusive? Excl.	Exclusive? Supp
	Nutren Junior	❑	❑	_____	_____	❑	❑
	Vital Junior	❑	❑	_____	_____	❑	❑
	Pediasure	❑	❑	_____	_____	❑	❑
	Ensure	❑	❑	_____	_____	❑	❑
	Modulen	❑	❑	_____	_____	❑	❑
	Peptamen	❑	❑	_____	_____	❑	❑
	Other:	❑	❑	_____	_____	❑	❑

Comments:

Paed-Intestinal Disease Collaboration Projects: Clinical Data at Enrollment

Participant Study Registration Number: **Gender:** *Male* *Female*

*(Affix your Subject ID barcode sticker OR handwrite your **Subject ID here**.*
SUBJECT ID MUST BE ON ALL PAGES.)

13e. Clinical Information at Enrollment

13 Was the participant recruited more than 6 months after diagnosis? ❑ Yes ❑ No

If 'yes' complete the following sections, if 'no' then data entry is complete, please go on to record sample details

13.1 Date of Enrollment ____ ____ / ____ ____ ____ / ____ ____ ____ ____ **14.1a Age at Enrollment**____ ____, ____ ____

dd **mmm** **yyyy** **yrs** **mths**

13.2 Diagnostic Impression at Enrollment: ❑ CD ❑ UC ❑ IBD-U ❑ Control (eg. Unaffected Relative)

14e. Participant Anthropometry at Enrollment

14.1 Anthropometrics:
Height (cm): _____ ❑ Clinic ❑ Self-reported Weight (kg):_____ ❑ Clinic ❑ Self-reported

Date these measurements were taken ____ ____ /____ ____ ____/ ____ ____ ____ ____
dd **mmm** **yyyy**

14.2 Tanner Stage:

❑ Physician assessed ❑ Self-reported ❑ Not assessed Breasts: 1 2 3 4 5 na Pubic Hair: 1 2 3 4 5 Genitalia: 1 2 3 4 5

14.2.1 Is the Participant Post-Menarchal? ❑Not Applicable ❑Yes ❑No ❑Unknown

Estimated Date of Menarche ____ ____ /____ ____ ____/ ____ ____ ____ ____
dd **mmm** **yyyy**

Participant Study Registration Number: **Gender:** *Male* *Female*

*(Affix your Subject ID barcode sticker OR handwrite your **Subject ID here**.*
SUBJECT ID MUST BE ON ALL PAGES.)

17. Review of Disease Location and Behaviour at Enrollment

38.1 Has Disease Location/Behaviour been Reassessed since Diagnosis? ❑ *No* ❑ *Yes*

If 'yes' complete the following questions, if 'no' then move to next section.

38.2 Approximate Date of Reassessment: __ __ / __ __ __ / __ __ __
dd mmm yyyy

38.4 Summary of Maximal Disease Location since Diagnosis:

Please indicate maximal disease involvement at all listed locations (tick one option only for each site)

	N	Mac	Mic	NA	U		N	Mac	Mic	NA	U
Oral	❑	❑	❑	❑	❑	Cecum	❑	❑	❑	❑	❑
Esophagus	❑	❑	❑	❑	❑	Asc Colon	❑	❑	❑	❑	❑
Stomach	❑	❑	❑	❑	❑	Trans Colon	❑	❑	❑	❑	❑
Duodenum	❑	❑	❑	❑	❑	Desc Colon	❑	❑	❑	❑	❑
Jej/Prox Ileum	❑	❑	❑	❑	❑	Sigmoid	❑	❑	❑	❑	❑
Distal Il/TI	❑	❑	❑	❑	❑	Rectum	❑	❑	❑	❑	❑

N= Normal *Mac = Macroscopic disease* *Mic = Microscopic Disease only* *NA = Not Assessed* *U = Unknown*

38.5 Stricturing/Fibrostenotic Behaviour status

Does the participant now (or at any time since Diagnosis) exhibit fixed Stricturing/Fibrostenotic disease behaviou?

❑ Yes ❑ No ❑ Unknown

If 'yes' then please complete the following section, if 'no' or 'unknown' proceed to next question

Approximate Date when first recognized to be present: __ __ / __ __ __ / __ __ ___
dd mmm yyyy

	Yes	No	
Features:	❑	❑	Constant luminal narrowing on DI, endo or surgery
	❑	❑	Pre-stenotic Dilatation
	❑	❑	Obstructive signs/symptoms

38.6 Internally Penetrating Behaviour status

Does the participant exhibit now (or at any time since diagnosis) Internally Penetrating disease behaviour?

❑ Yes ❑ No ❑ Unknown

If 'yes' then please complete the following section, if 'no' or 'unknown' proceed to next section

Approximate Date when first recognized to be present: __ __ / __ __ __ / __ __ ___
dd mmm yyyy

	Yes	No	
Features:	❑	❑	Entero-enteric or entero-vesicular fistula/e
	❑	❑	Entero-cutaneous fistula/e
	❑	❑	Intra-abdominal abscess/es
	❑	❑	Intestinal Perforation

Comments:

Paed-Intestinal Disease Collaboration Projects: Perianal Disease at Enrollment

Participant Study Registration Number: **Gender:** *Male* *Female*

*(Affix your Subject ID barcode sticker OR handwrite your **Subject ID here**.*
SUBJECT ID MUST BE ON ALL PAGES.)

39. Update of Perianal Disease History at Enrollment

37.2 Record of Perianal Disease Development since diagnosis until enrolment?

		Recognized at Diagnosis?			Newly recognized since diagnosis? (Leave blank if recognized previously)			
		Yes	*No*	*Unknown*	*No*	*Unknown*	*Yes*	Approx Date First Recognized
37.2.1	Large Skin Tags	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.2.2	Ulcers	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.2.3	Fissure/s	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.2.4	Isolated Abscess	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.2.5	Multiple Abscesses	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.2.6	Perianal Fistula/e	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.2.7	Recto-vaginal Fistula/e	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)
37.2.8	Ano-vaginal Fistula/e	❑	❑	❑	❑	❑	❑	__ __ / __ __ __ / __ __ __ __ (dd / mmm / yyyy)

Paed-Intestinal Disease Collaboration Projects: Treatment Data at Enrollment (1)

Participant Study Registration Number: **Gender:** *Male* *Female*

*(Affix your Subject ID barcode sticker OR handwrite your **Subject ID here**.*
SUBJECT ID MUST BE ON ALL PAGES.)

41 Summary of Treatment at Enrollment

Treatment	Received Since Diagnosis? No	Yes	Start Date	Dose (mg)	Still Ongoing? No	Stop Date	Yes	Current Dose: Current Daily Dose (mg)
Supplements etc								
Probiotic	❑	❑	_____	XXXXXX	❑	_____	❑	XXXXXXXXXXXX
Omega-3	❑	❑	_____	XXXXXX	❑	_____	❑	XXXXXXXXXXXX
Oral 5-ASA								
Sulfasalazine	❑	❑	_____	_____	❑	_____	❑	_____
Mesalazine	❑	❑	_____	_____	❑	_____	❑	_____
Olsalazine	❑	❑	_____	_____	❑	_____	❑	_____
Antibiotics								
Metronidazole (Flagyl)	❑	❑	_____	_____	❑	_____	❑	_____
Ciprofloxacin	❑	❑	_____	_____	❑	_____	❑	_____
Rifaxamin (Xifaxin)	❑	❑	_____	_____	❑	_____	❑	_____
Corticosteroids								
MethylPrednisone	❑	❑	_____	_____	❑	_____	❑	_____
Hydrocortisone IV	❑	❑	_____	_____	❑	_____	❑	_____
Prednisone or Prednisolone	❑	❑	_____	_____	❑	_____	❑	_____
Oral Budesonide	❑	❑	_____	_____	❑	_____	❑	_____
Immunomodulators								
Azathioprine	❑	❑	_____	_____	❑	_____	❑	_____
6-Mercaptopurine	❑	❑	_____	_____	❑	_____	❑	_____
Tacrolimus	❑	❑	_____	_____	❑	_____	❑	_____
Cyclosporin	❑	❑	_____	_____	❑	_____	❑	_____

	Received Since Diagnosis? No	Yes	Start Date	Dose (mg)	Freq	Still Ongoing? No	Stop Date	Yes	Change Dose or Frequency? No	Yes	Date	Dose(mg)	Freq
Methotrexate (SC/IM)	❑	❑	_____	_____	_____	❑	_____	❑	❑	❑	_____	_____	____
Methotrexate (Oral)	❑	❑	_____	_____	_____	❑	_____	❑	❑	❑	_____	_____	____
Biologic Agent													
Adalimumab	❑	❑	_____	_____	_____	❑	_____	❑	❑	❑	_____	_____	____
									❑	❑	_____	_____	____
									❑	❑	_____	_____	____
									❑	❑	_____	_____	____
Certolizumab	❑	❑	_____	_____	_____	❑	_____	❑	❑	❑	_____	_____	____
									❑	❑	_____	_____	____
									❑	❑	_____	_____	____

	Received Since Diagnosis? No	Yes	Start Date	Dose (mg)	Still Ongoing? No	Yes	Date Received	Dose(mg)
Infliximab	❑	❑	_____	_____	❑	❑	_____	_____
							_____	_____
							_____	_____
							_____	_____
Natalizumab	❑	❑	_____	_____	❑	❑	_____	_____
							_____	_____

Paed-Intestinal Disease Collaboration Projects: Rx & Ix Data at Enrollment (2)

Participant Study Registration Number: **Gender:** *Male* *Female*

*(Affix your Subject ID barcode sticker OR handwrite your **Subject ID here**.*
SUBJECT ID MUST BE ON ALL PAGES.)

42. Summary of Enteral Therapy since Diagnosis

	Received Since Diagnosis?			**Still Ongoing?**			**Change Dose?**			
Treatment	*No*	*Yes*	**Start Date** / **Est Cal/day**	*No*	**Stop Date**	*Yes*	*No*	*Yes*	**Date**	**Est. Cal/day)**
Exclusive										
Nutren Junior	❑	❑	_____ _____	❑	_____	❑	❑	❑	_____	_____
Vital Junior	❑	❑	_____ _____	❑	_____	❑	❑	❑	_____	_____
Pediasure	❑	❑	_____ _____	❑	_____	❑	❑	❑	_____	_____
Ensure	❑	❑	_____ _____	❑	_____	❑	❑	❑	_____	_____
Modulen	❑	❑	_____ _____	❑	_____	❑	❑	❑	_____	_____
Peptamen	❑	❑	_____ _____	❑	_____	❑	❑	❑	_____	_____
Other:										
	❑	❑	_____ _____	❑	_____	❑	❑	❑	_____	_____
Supplemental										
Nutren Junior	❑	❑	_____ _____	❑	_____	❑	❑	❑	_____	_____
Vital Junior	❑	❑	_____ _____	❑	_____	❑	❑	❑	_____	_____
Pediasure	❑	❑	_____ _____	❑	_____	❑	❑	❑	_____	_____
Ensure	❑	❑	_____ _____	❑	_____	❑	❑	❑	_____	_____
Modulen	❑	❑	_____ _____	❑	_____	❑	❑	❑	_____	_____
Peptamen	❑	❑	_____ _____	❑	_____	❑	❑	❑	_____	_____
Other:										
	❑	❑	_____ _____	❑	_____	❑	❑	❑	_____	_____

43. General Comments

Please note anything else you feel may be relevant or should be considered (not listed elsewhere on this form):

Paed-Intestinal Disease Collaboration Projects: Study Specific Sample Collection (1)

Participant Study Registration Number: **Gender:** *Male* *Female*

*(Affix your Subject ID barcode sticker OR handwrite your **Subject ID here**.*
SUBJECT ID MUST BE ON ALL PAGES.)

21. Study Specific Investigations/Procedures to be completed at Enrollment

Sample Type *(circle one for each sample)* **:**

1.	Red Top	Mustard Top	Stool	Resection	Date Collected (dd/mmm/yyyy): _____
	Purple Top	Speckled Top	Urine	Other	
	Green Top	PaxGene RNA tube	Biopsy		affix Sample ID barcode sticker OR handwrite Subject/Sample ID here
	Additional Sample Details: *(eg. Bx location + if affected/unaffected)*				*(each sample container needs a unique barcode)*
2.	Red Top	Mustard Top	Stool	Resection	Date Collected (dd/mmm/yyyy): _____
	Purple Top	Speckled Top	Urine	Other	
	Green Top	PaxGene RNA tube	Biopsy		affix Sample ID barcode sticker OR handwrite Subject/Sample ID here
	Additional Sample Details: *(eg. Bx location + if affected/unaffected)*				*(each sample container needs a unique barcode)*
3.	Red Top	Mustard Top	Stool	Resection	Date Collected (dd/mmm/yyyy): _____
	Purple Top	Speckled Top	Urine	Other	
	Green Top	PaxGene RNA tube	Biopsy		affix Sample ID barcode sticker OR handwrite Subject/Sample ID here
	Additional Sample Details: *(eg. Bx location + if affected/unaffected)*				*(each sample container needs a unique barcode)*
4.	Red Top	Mustard Top	Stool	Resection	Date Collected (dd/mmm/yyyy): _____
	Purple Top	Speckled Top	Urine	Other	
	Green Top	PaxGene RNA tube	Biopsy		affix Sample ID barcode sticker OR handwrite Subject/Sample ID here
	Additional Sample Details: *(eg. Bx location + if affected/unaffected)*				*(each sample container needs a unique barcode)*
5.	Red Top	Mustard Top	Stool	Resection	Date Collected (dd/mmm/yyyy): _____
	Purple Top	Speckled Top	Urine	Other	
	Green Top	PaxGene RNA tube	Biopsy		affix Sample ID barcode sticker OR handwrite Subject/Sample ID here
	Additional Sample Details: *(eg. Bx location + if affected/unaffected)*				*(each sample container needs a unique barcode)*