CD Risk Prediction: Registration and Eligibility

1. Patient Registration for the CD Risk Prediction Study

Patient Study Registration Number ☐☐-☐☐☐ **(Affix Barcode Sticker if Available)**

***Patient First Name:** _____ ***Patient Family Name:** _____

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

**** These three (3) fields are NOT mandatory***

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

2. Reminder of Eligibility Requirements for the CD Risk Prediction Study

2.1 Is the patient younger than 17 years of age?	❑Yes	❑No	❑Unknown
2.2 Will the patient undergo upper GI endoscopy?	❑Yes	❑No	❑Unknown
2.3 Will the Ileum be visualized either radiologically and/or endoscopically?	❑Yes	❑No	❑Unknown
2.4 Do both the patient and physician anticipate that the subject will be available for follow-up at this centre for a minimum of 36 months?	❑Yes	❑No	❑Unknown
2.5 Will it be possible to obtain appropriate consent?	❑Yes	❑No	❑Unknown
2.6 Is the patient and their family willing to provide consent/assent for the collection of biological samples including DNA?	❑Yes	❑No	❑Unknown

If the response to any of the above questions is "no" or "unknown" it is likely that the subject is NOT eligible for participation in this study, please discuss with the site-PI.

3. Reminder of Exclusion Criteria for the CD Risk Prediction Study

3.1 Is the patient thought to have Ulcerative Colitis?	❑Yes	❑No	❑Unknown
3.2 At Diagnosis, is there evidence of Fibrostenotic/Penetrating Disease?	❑Yes	❑No	❑Unknown
3.3 Has the patient undergone luminal bowel resection?	❑Yes	❑No	❑Unknown
3.4 Has the patient a documented and persistent intestinal infection?	❑Yes	❑No	❑Unknown

If the response to any of the above questions is "yes", it is likely that the subject is NOT eligible for participation in this study, please discuss with the site-PI.

CD Risk Prediction: Consent and Enrollment

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female*

(Or affix Barcode Sticker if Available)

4. Study Consent Procedures

4.1 Was consent obtained ❑Yes ❑No

4.2 Date consent was obtained ___ ___ /___ ___ ___/ ___ ___ ___ ___
dd **mmm** **yyyy**

4.3 Consent Version Date ___ ___ /___ ___ ___/ ___ ___ ___ ___
dd **mmm** **yyyy**

4.4 Signee:
❑Subject ❑Mother ❑Father ❑Both Parents ❑Legal Guardian ❑Other

4.5 Was assent obtained ❑Yes ❑No

4.6 Date assent was obtained ___ ___ /___ ___ ___/ ___ ___ ___ ___
dd **mmm** **yyyy**

4.7 Assent Version Date ___ ___ /___ ___ ___/ ___ ___ ___ ___
dd **mmm** **yyyy**

5. Enrollment

***5.1* Study Enrollment Date** ____ ____ /____ ____ ____/ ____ ____ ____ ____
dd **mmm** **yr**

5a Confirmation of Enrollment Registration on Database

***5.2* Record the System Generated CD Risk Stratification Study Unique Enrollment Number here:**
(NB: This number is displayed on Workflow Number 1 "Patient Registration")

☐☐☐☐☐☐

(This is NOT the Patient Registration Bar-code Number or the 'Tempo' Identifier Number, but a unique number that will be provided by the DCC following registration of the patient's enrollment on the database)

Comments from Registration Process

CD Risk Prediction: Confirmation of Diagnosis

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female*

(Or affix Barcode Sticker if Available)

6. Does the Patient meet the study's diagnostic definition of CD?

To meet the study's definition of 'Crohn's Diease' or 'IBD-U', the subject must eventually be found to have at least ONE FEATURE from TWO of the CATEGORIES listed below.

6.1 Indicate which of the following features were apparent at the time of the patient being enrolled in this study

Y = Yes N = No U = Unknown

6.1.1) History of the following:

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

6.1.2) Endoscopic Findings (includes capsule endoscopy):

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

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

6.1.3) Radiological Findings:

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

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

6.1.4) Laparotomy Findings (NB: intestinal resection is an exclusion criteria for this study):

❑ Not applicable

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

6.1.5) 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	❑	❑	❑

***6.2* At the time of enrollment, did this subject meet the study's definition of CD/IBD-U? ❑ Yes ❑ No**

If 'No":

1) ***Participants MAY continue in this study even when the requirements of the above definition are NOT met.***
2) ***Diagnostic eligibility must be reviewed again at the first follow-up visit***

***6.3* By 1st follow-up review, did this subject meet the study's definition of CD/IBD-U? ❑ Yes ❑ No**

If 'No":

If the patient does NOT fulfill the study's diagnostic definition requirements by the first follow-up visit, then it is possible that the subject is no longer eligible for participation in this study; please discuss with a Study PI.

***6.4* Name of Study PI contacted: _____ Deemed Eligible for Study? ❑ Yes ❑ No**

Comments:

CD Risk Prediction: Demographics and History Summary (1)

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female*

(Or affix Barcode Sticker if Available)

7. Patient's Ethnic Demographics

7.1 Patient's country of birth: _____ *7.2* Estimated date of arrival in present country : ❑N/A _____

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

	Stated Racial Background (textual)	*Stated Jewish Background*					*Stated Hispanic Background*		
		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

9. Patient's Birth History

Mode of delivery:

9.1 Was the patient delivered by caesarean section? ❑Yes ❑No ❑Unknown

Patient's milk source as an infant:

9.2 Was the patient ever Breast Fed? ❑Yes ❑No ❑Unknown

If 'yes':

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

10. Patient Environmental and Medical History

Cigarette Smoke Exposure:

10.1.1 Was the patient a current smoker around the time of Dx? ❑Yes ❑No ❑Unknown

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

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

10.1.4 Did the patient's biological mother smoke during pregnancy? ❑Yes ❑No ❑Unknown

Appendectomy:

10.2 Has the patient undergone an appendectomy? ❑Yes ❑No ❑Unknown

If 'yes':

10.2.1 Approximate date of appendectomy ____ ____ /____ ____ ____/ ____ ____ ____ ____

dd **mmm** **yyyy**

Previous Gastrointestinal Infection:

Did the patient have a severe gastrointestinal infection (eg: C difficile, Salmonella etc):

10.3.1 Within 6 months prior to Dx? ❑Yes ❑No ❑Unknown

10.3.2 At anytime more than 6 months prior to Dx? ❑Yes ❑No ❑Unknown

Non-steroidal Anti-inflammatory Drug Exposure:

10.4 Did the patient receive NSAIDs anytime during the 6 month period prior to Dx? ❑Yes ❑No ❑Unknown

If 'yes':

10.4.1 Approximate number of doses: ❑ <3 doses ❑ 3-6 doses ❑ 7-20 doses ❑ 21-30 doses ❑ >30 doses

CD Risk Prediction: Demographics and History Summary (2)

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female*

(Or affix Barcode Sticker if Available)

11. Summary of Familial History of IBD

Does any member of the subject'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	❑	❑	❑	❑	❑	❑

Comments:

12. Summary of Personal and Family History

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

	Patient			**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 Spoindylitis				❑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)

13. Summary of Extra Intestinal Manifestations observed in this Subject

	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:

CD Risk Prediction: Clinical Data at Diagnosis

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female*

(Or affix Barcode Sticker if Available)

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 Enrollment: ❑ CD ❑ UC ❑ IBD-U ❑ Not IBD

15. Historical Anthropometric Data

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

Parent's Height:

Biological Mother: _____ cm
(Data unobtainable ❑)

Biological Father: _____ cm
(Data unobtainable ❑)

Date *(dd / mmm / yyyy)*	Height (cm)	Weight (kg)
__ __ / __ __ __ / __ __ __ __		
__ __ / __ __ __ / __ __ __ __		
__ __ / __ __ __ / __ __ __ __		
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16. Patient 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 Patient Post-Menarchal? ❑Not Applicable ❑Yes ❑No ❑Unknown

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

17. Physician Assessment at Diagnosis

17.1 Physician Global Assessment of Disease Activity around the time of Diagnosis:

❑ None ❑ Mild ❑ Moderate ❑ Severe

(Don't forget to complete the PCDAI or PUCAI)

CD Risk Prediction: PCDAI at Diagnosis

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female*

(Or affix Barcode Sticker if Available)

18a. Disease Activity Data Recorded at diagnosis

18.1 How was this data collected? ❑ Clinic Visit ❑ Telephone Interview ❑ Assessment not done

18.2 Date of Assessment ___ ___ / ___ ___ ___ / ___ ___ ___ ___
dd **mmm** **yyyy** **Comments:**

18.3 Which Activity Index Tool was used? ❑ PCDAI ❑ PUCAI

18b. History (Recall over past 7 days)

Most Severe Abdominal Pain
❑ None ❑ Mild: Brief, does not interfere with activities ❑ Mod/Severe: Daily, longer lasting, affects activities, nocturnal

Stools (per day)
❑ 0-1 liquid stools, no blood ❑ Up to 2 semi-formed + small blood, or 2-5 liquid +/- blood ❑ Gross bleeding, or >/= 6 liquid, or nocturnal diarrhea

Patient Functioning, General Well-being
❑ No limitation of activities, well ❑ Occasional difficulty in maintaining age appropriate activities, below par ❑ Frequent, limitation of activity very poor

18c. Examination

Weight
❑ Weight gain or voluntary weight stable/loss ❑ Involuntary weight stable, weight loss 1-9% ❑ Weight oss >/= 10%

Height
Height approximately 12 months ago: Date Taken: __ __ / __ __ __ / __ __ __ __ (d d m m m y y y y) Height (cm) _____

❑ < 1 channel decrease in Ht OR Ht Vel z-score <= -1 ❑ >= 1 and < 2 channel decrease in Ht OR Ht Vel z-score -1 to <-2
❑ > 2 channel decrease in Ht OR Ht Vel z-score >= -2

Abdomen

	Yes	*No*		*Yes*	*No*		*Yes*	*No*
Tenderness	❑	❑	Mass	❑	❑	Involuntary guarding	❑	❑

Perirectal Disease

	Yes	*No*		*Yes*	*No*		*Yes*	*No*
Asymptomatic tags	❑	❑	Fissure	❑	❑	Active Fistula or abscess	❑	❑
Inflamed tags	❑	❑	Indolent fistula	❑	❑	Drainage or Tenderness	❑	❑

Extra-Intestinal Manifestations

	Yes	*No*		*Yes*	*No*		*Yes*	*No*
Fever >/= 38.5oC for 3 days over past week	❑	❑	Uveitis	❑	❑	E Nodosum	❑	❑
Oral Ulcers	❑	❑	Definite Arthritis	❑	❑	P. gangrenosum	❑	❑

18d. Investigations Required to complete Index *(Values obtained within the last week)*

	Requested	**Collected/Performed**	**Not Available**	**(Record result under "Core Investigations")**
HCT (%):	❑	❑	❑	
ESR (mm/hr):	❑	❑	❑	
Albumin (g/dL):	❑	❑	❑	

Comments:

CD Risk Prediction: PUCAI© at Diagnosis

DISREGARD this entire page if completing PCDAI form

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female*

(Or affix Barcode Sticker if Available)

18a. Disease Activity Data Recorded at diagnosis

18.1 How was this data collected? ❑ Clinic Visit ❑ Telephone Interview ❑ Assessment not done

18.2 Date of Assessment ___ ___ / ___ ___ ___ / ___ ___ ___ ___

dd **mmm** **yyyy** **Comments:**

18.3 Which Activity Index Tool was used? ❑ PCDAI ❑ PUCAI

18e. History (Last 24 hours)

1. Abdominal Pain

❑ No Pain ❑ Pain can be ignored ❑ Pain cannot be ignored

2. Rectal Bleeding

❑ None ❑ Small amount only, in less than 50% of stools

❑ Small amount with most stools ❑ Large amount (>50% of the stool content)

3. Stool Consistency of most stools

❑ Formed ❑ Partially Formed ❑ Completely unformed

4. Number of stools per 24 hours

❑ 0 – 2 ❑ 3 - 5 ❑ 6 – 8 ❑ > 8

5. Nocturnal stools (any episode causing wakening)

❑No ❑ Yes

6. Activity Level

❑ No limitation of activity ❑ Occasional limitation of activity ❑ Severely restricted activity

Comments:

CD Risk Prediction: Location and Behaviour Data at Diagnosis

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female*

(Or affix Barcode Sticker if Available)

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	❑	❑	❑
Internally Penetrating	❑	❑	❑

If the response to either of the above questions is "yes" or "unknown" it is likely that the subject is NOT eligible for participation in this study, please discuss with the site-PI.

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	❑	❑	❑

CD Risk Prediction: Endoscopic Activity Score at Diagnosis

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female*

(Or affix Barcode Sticker if Available)

23. Endoscopy Assessment of Disease at Diagnosis (CDEIS)

Please indicate endoscopic disease involvement at all listed locations as described below

How was this data collected?

❑ Not Obtainable ❑ Retrospective Chart Review ❑ Proceduralist (Retrospective) ❑ Proceduralist (Contemporaneous)

Date of Endoscopic Assessment ___ ___ / ___ ___ ___ / ___ ___ ___ ___

dd **mmm** **yyyy**

	Assessed		Deep Ulceration		Superficial Ulceration		Amount of Surface Involved (%)	Amount of Surface Ulcerated (%)	Photo Avail		Up-loaded
	Y	N	Y	N	Y	N			N	Y	
Rectum	❑	❑	❑	❑	❑	❑	_____	_____	❑	❑	❑
Sigmoid	❑	❑	❑	❑	❑	❑	_____	_____	❑	❑	❑
Desc. Colon	❑	❑	❑	❑	❑	❑	_____	_____	❑	❑	❑
Trans. Colon	❑	❑	❑	❑	❑	❑	_____	_____	❑	❑	❑
Rgt. Colon	❑	❑	❑	❑	❑	❑	_____	_____	❑	❑	❑
Ileum	❑	❑	❑	❑	❑	❑	_____	_____	❑	❑	❑

	Y	N
Was there an area of ulcerated stenosis anywhere?	❑	❑
Was there an area of non-ulcerated stenosis anywhere?	❑	❑

Y= Yes N = No

Comments:

CD Risk Prediction: Treatment Data at Diagnosis

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female*

(Or affix Barcode Sticker if Available)

24. Treatment around the time of Diagnosis

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

Category	Name	Received *No*	Received *Yes*	Start Date *(dd/mmm/.yyyy)*	Initial Daily Dose *(mg)*
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:

CD Risk Prediction: Core Investigation Data at Diagnosis

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female*

(Or affix Barcode Sticker if Available)

25. Summary of Core Laboratory Investigations at Diagnosis

Date of Blood Draw ____ ____ /____ ____ ____/ ____ ____ ____ ____ **Lab Used** _____

dd **mo** **yr**

	Performed			**Result**		**Performed**			**Result**
Hemoglobin (g/dL)	❑Y	❑N	❑U	_____	*CRP* (mg/L)	❑Y	❑N	❑U	_____
HCT (%)	❑Y	❑N	❑U	_____	*Albumin* (g/dL)	❑Y	❑N	❑U	_____
Platelet Count (10^9/L)	❑Y	❑N	❑U	_____	*Urea (mmol/L)*	❑Y	❑N	❑U	_____
White Cell Count (10^9/L)	❑Y	❑N	❑U	_____	*Creatinine (micromol/L)*	❑Y	❑N	❑U	_____
Neutrophil (10^9/L)	❑Y	❑N	❑U	_____	*AST (U/L)*	❑Y	❑N	❑U	_____
Lymphocytes (10^9/L)	❑Y	❑N	❑U	_____	*ALT (U/L)*	❑Y	❑N	❑U	_____
Eosinophil (10^9/L)	❑Y	❑N	❑U	_____	*Alk Phos (U/L)*	❑Y	❑N	❑U	_____
ESR (mm/hr)	❑Y	❑N	❑U	_____	*GGT (U/L)*	❑Y	❑N	❑U	_____

Y= Yes, N= No, U=Unknown

CD Risk Prediction: Study Specific Sample Collection at Diagnosis

Patient Registration Number ☐☐-☐☐☐ **Gender:** *Male* *Female*

(Or affix Barcode Sticker if Available)

26. Study Specific Investigations/Procedures to be completed this visit

Serology:

❑ *Will not be collected* ❑ *Requested* ❑ *Collected/performed*

Date Collected (dd/mmm/yyyy): _____ Sample ID: _____ (Barcode Identity)

DNA:

❑ *Will not be collected* ❑ *Requested* ❑ *Collected/performed*

Date Collected (dd/mmm/yyyy): _____ Sample ID: _____ (Barcode Identity)

Stool:

❑ *Will not be collected* ❑ *Requested* ❑ *Collected/performed*

Date Collected (dd/mmm/yyyy): _____ Sample ID: _____ (Barcode Identity)

26a. Mucosal Biopsy Sub-Study Sample Collection

Mucosal Biopsy #1:

❑ *Will not be collected* ❑ *Requested* ❑ *Collected/performed*

Anatomical Site: _____

Date Collected (dd/mmm/yyyy): _____ Sample ID: _____ (Barcode Identity)

Mucosal Biopsy #2:

❑ *Will not be collected* ❑ *Requested* ❑ *Collected/performed*

Anatomical Site: _____

Date Collected (dd/mmm/yyyy): _____ Sample ID: _____ (Barcode Identity)

Mucosal Biopsy #3:

❑ *Will not be collected* ❑ *Requested* ❑ *Collected/performed*

Anatomical Site: _____

Date Collected (dd/mmm/yyyy): _____ Sample ID: _____ (Barcode Identity)

Mucosal Biopsy #4:

❑ *Will not be collected* ❑ *Requested* ❑ *Collected/performed*

Anatomical Site: _____

Date Collected (dd/mmm/yyyy): _____ Sample ID: _____ (Barcode Identity)

Mucosal Biopsy #5:

❑ *Will not be collected* ❑ *Requested* ❑ *Collected/performed*

Anatomical Site: _____

Date Collected (dd/mmm/yyyy): _____ Sample ID: _____ (Barcode Identity)

Mucosal Biopsy #6:

❑ *Will not be collected* ❑ *Requested* ❑ *Collected/performed*

Anatomical Site: _____

Date Collected (dd/mmm/yyyy): _____ Sample ID: _____ (Barcode Identity)

PCDAI USER'S GUIDE

This guide is intended to help nurse coordinators and physicians complete the PCDAI in order to assess disease activity in children with Crohn's disease participating in clinical trials.

HISTORY

All calculations are based upon a 1 week (7 day) history recall of symptoms. The history recall should be solicited from the patient and/or caregiver.

1. **Abdominal pain**

The descriptions in the PCDAI of "mild" and "moderate/severe" should be used to guide in scoring the pain. Note that duration, effect on activities, and nocturnal occurrence separate moderate/severe from mild. If pain varies in severity during the week, patient should be scored according to the most severe pain. However, mild pain should be present on at least two days to score 5 points rather than 0 points.

2. Stools

The intent is to score the stool pattern during the preceding week.

To facilitate scoring, first categorize the patient as having blood in the stool or not.

If there is **no blood** in the stool, score as follows:

Formed stools or up to 1 loose stool daily = 0

2-5 liquid or very loose stools on 1 or more days = 5

6 or more liquid or very loose stools on 1 or more days or any nocturnal diarrhea = 10

If **blood** is present in the stool on any day during the past week, score as follows:

Small amounts of blood in stool (on toilet paper or small spots in stool, etc.) = 5

Any gross bleeding (large amounts on stool or colors the water in the toilet, etc.) = 10

3. Patient functioning, general well-being

If there is variation during the week, patient should be scored according to the most significant limitation of activity, even if only one day of the week, as long as likely due to Crohn's disease and not to an intercurrent illness.

PHYSICAL EXAMINATION

4.Weight (The intent is to assess the ability to normally maintain or gain weight)

Voluntary weight stable/loss means patient maintaining or losing weight on purpose.

Involuntary weight stable means patient wants to gain weight but cannot.

To calculate percentage weight loss use formula:

$$\frac{\text{Historic weight} - \text{Current weight}}{\text{Historic weight}} \times 100 = \%\ \text{weight loss}$$

Take historic weight as maximal weight attained within preceding 4-6 months, excluding any value that reflects excess weight due to corticosteroid use.

5. Height The intent is to assess the normalcy vs impairment of the patient's recent linear growth. Note that post-pubertal patients will score 0 points. For patients still growing, there are two options for scoring. Method (a) is preferred. Method (b) to be used if data required for (a) are unavailable.

a) Height velocity (cm/year), the most sensitive parameter, should be used if reliable height measurements are available from the preceding 6 to 12 months.

Convert height increment during preceding 6 to 12 months into velocity (cm/year) as follows:

$$\frac{\text{Present height} - \text{Height 6 – 12 months previously}}{\text{Interval (months) between heights}} \times 12 = \text{Height velocity (cm/year)}$$

Using height velocity chart, which accompanies PCDAI, determine centile for height velocity.

Height velocity should ideally be plotted according to bone age rather than chronologic age. However, if maturity is appropriate for age (not delayed or advanced) it is reasonable to plot and score height velocity according to chronologic age.

In follow-up visits of short-term clinical trials less than 4 months duration, score height velocity the same as the initial score unless there has been an actual height gain.

b) If reliable height measurements from 6 to 12 months previously are lacking (often the case with newly diagnosed patients), use any earlier heights to assess previous height centile and compare with current height centile. Score according to degree of decrease in height centile.

PCDAI: *see instructions previous page re: scoring items marked *

HISTORY (Recall; 1 week)*

Abdominal pain:* None _____(0)
Mild – Brief, does not interfere with activities _____ (5)
Mod / severe - daily, longer lasting, affects activities, nocturnal _____ (10)

Stools*: (per day)
Formed stools or up to 1 liquid stool, no blood _____ (0)
Up to 2 semi-formed with small blood, or 2-5 liquid with or without small blood _____ (5)
Any gross bleeding, or ≥ 6 liquid, or nocturnal diarrhea _____ (10)

Patient Functioning* – General Well-Being

No limitation of activities, well _____ (0)
Occasional difficulty in maintaining appropriate activities, below par _____ (5)
Frequent limitation of activity, very poor _____ (10)

LABORATORY (values obtained within the past week)

HCT (%)	< 10 yrs :	>33	____ (0)
		28-32	____ (2.5)
		< 28	____ (5)
	Males 11-14yrs	>35	____ (0)
		30-34	____ (2-5)
		< 30	____ (5)
	Males 15-19yrs:	≥37	____ (0)
		32-36	____ (2.5)
		< 32	____ (5)
	Females 11-19yrs	≥ 34	____ (0)
		29-33	____ (2.5)
		< 29	____ (5)
ESR (mm/hr)		< 20	____ (0)
		20-50	____ (2.5)
		> 50	____ (5)
ALBUMIN (g/dL)		≥ 3.5	____ (0)
		3.1-3.4	____ (5)
		≤ 3.0	____ (10)

TOTAL SCORE _____

EXAMINATION

Weight*
Weight gain or voluntary weight stable/loss _____ (0)
Involuntary weight stable, weight loss 1-9% _____ (5)
Weight loss ≥ 10% _____ (10)

Height* Score using (a) criteria when possible

a) Height velocity ≥ -1SD _____ (0)
Height velocity < - 1SD, >-2SD _____ (5)
Height velocity ≤ - 2SD _____ (10)

OR

b) < 1 channel decrease _____ (0)
≥1, < 2 channel decrease _____ (5)
> 2 channel decrease _____ (10)

Abdomen

No tenderness, no mass _____ (0)
Tenderness, or mass without tenderness _____ (5)
Tenderness, involuntary guarding, definite mass _____ (10)

Perirectal disease

None, asymptomatic tags _____ (0)
Inflamed tags or 1-2 indolent fistula(e) or fissure(s), scant drainage, no tenderness _____ (5)
Active fistula, drainage, tenderness, or abscess _____ (10)

Extra-intestinal Manifestations

(Fever ≥ 38.5 for 3 days over past week, oral ulcers definite arthritis, uveitis, E.nodosum, P. gangrenosum)
None _____ (0)
One _____ (5)
≥ Two _____ (10)