IBD biorepository sample database

Record ID

_____

Sample number (unique)

_____
(unique identifier for each individual sample)

Label on sample

_____

Medical record number

_____
(subjects without CHMR get 9999999)

Biorepository ID number

_____
(relatives get 1 decimal place (mom=.2, dad=.3, sibs = later decimals))

Who completed this CRF?

○ Alex
○ Anastasia
○ Kate
○ Knox
○ Sarah
○ Sean
○ Spencer
○ Sophia
○ Tamar

Date CRF was completed

_____

Date sample was obtained

_____

Did the patient consent for the registry?

○ Yes
○ No

Did the patient consent for the biorepository?

○ Yes
○ No
(Has patient consented for Snapper biorepository, or was sample obtained previously under an older protocol and grandfathered in?)

Prior protocol sample was obtained under

○ CHIMP (X06-10-0470)
○ Oral microbiome (X09-10-0535)
○ Grand Lee Genetics (04-12-173R)
○ Bousvaros Immunoregulation (98-12-206R)
(If sample was grandfathered in from another protocol)

Is sample collected from a patient with IBD?

○ IBD patient
○ Control patient
○ Family member
(This field will utilize branching to determine if sample is from an IBD patient, control patient, or family member of IBD patient)

If patient has IBD, what type?

○ Crohn's disease
○ Ulcerative Colitis
○ Indeterminate colitis (IBD-U)
○ IBD in transplant patient
○ Autommune enteropathy
○ Other

Other IBD diagnosis

_____
(this is only for unusual IBD phenotypes)

Is there any family history of IBD? ⃝ Yes
⃝ No

Which family member(s)? ☐ Mother
☐ Father
☐ Full brother
☐ Full sister
☐ 2nd degree relative
☐ Other

Which relative? _____

Does the patient have an immunodeficiency? ⃝ Chronic granulomatous disease
⃝ IL-10 receptor deficiency
⃝ IPEX
⃝ NEMO mutation
⃝ Wiskott Aldrich
⃝ X-Linked Agammaglobulinemia
⃝ Other
⃝ None

What immunodeficiency? _____

Control diagnosis (primary) ⃝ Allergic colitis
⃝ Celiac disease
⃝ Clostridium difficile infection
⃝ Congenital Enteropathy
⃝ Constipation
⃝ Diarrhea
⃝ Eosinophilic Esophagitis
⃝ Functional abdominal pain
⃝ GERD or Reflux
⃝ Healthy control without GI disease
⃝ Hirschsprung's
⃝ H. pylori
⃝ Immunodeficiency without IBD
⃝ Irritable bowel syndrome
⃝ Microscopic colitis
⃝ Perianal disease
⃝ Polyps
⃝ Primary sclerosing cholangitis
⃝ Rectal Bleeding
⃝ Other

Control diagnosis if "other" _____

What immunodeficiency? ⃝ Chronic granulomatous disease
⃝ IL-10 receptor deficiency
⃝ IPEX
⃝ NEMO mutation
⃝ Wiskott Aldrich
⃝ X-Linked Agammaglobulinemia
⃝ Other

Which immunodeficiency? _____

Does the patient have primary sclerosing cholangitis? ⃝ Yes
⃝ No

Family member type ⃝ Mother
⃝ Father
⃝ Brother
⃝ Sister
⃝ Other

Family member GI diagnosis

- ○ Healthy without GI problems
- ○ Celiac disease
- ○ Constipation
- ○ Crohn Disease
- ○ Irritable Bowel Syndrome
- ○ Ulcerative Colitis
- ○ Other

What diagnosis?

_____

Patient's gender

- ○ Female
- ○ Male
- ○ Unknown

Patient's date of birth

_____

Patient's age (years)

_____

What is the patient's race?

- ☐ Alaska Native
- ☐ American Indian
- ☐ Asian
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Black or African American
- ☐ White/Caucasian

Is the patient of Hispanic or Latino origin?

- ○ Yes
- ○ No

Is this a VEOIBD sample?

- ○ Yes
- ○ No

What's the CHB ID?

_____

Is this a VEOIBD proband?

- ○ Yes
- ○ No

Is this a Boston Children's Hospital participant?

- ○ Yes
- ○ No

What is the referring hospital?

_____

Who is referring physician?

_____

When did symptoms start?

_____

When was the patient diagnosed?

_____

Is there a family history of consanguinity?

- ○ Yes
- ○ No

Does the patient have a history of oral or perianal disease?

- ☐ Oral
- ☐ Perianal

NSAID exposure within the last six months?

- ○ Yes
- ○ No

How many doses of NSAIDs?

- ○ < 3
- ○ 3-6
- ○ 7-20
- ○ 21-30
- ○ >30

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REDCap

Type of sample

   ◯ Blood
   ◯ Fecal
   ◯ GI Biopsy
   ◯ Oral swab
   ◯ Resected tissue
   ◯ Saliva
   ◯ Urine
   ◯ Other
   (Type of sample acquired)

What kind of sample?

_____

Was this a one-time sample?

   ◯ Longitudinal sample
   ◯ One-time sample

Which blood samples were collected?

   ☐ DNA
   ☐ PAX gene
   ☐ PBMCs
   ☐ Serum
   ☐ Sodium heparin tube
   ☐ Whole blood

How long until the fecal sample was frozen at -20?

   ◯ Frozen at -20 within 4 hours
   ◯ Frozen at -20 within 12 hours
   ◯ Frozen at -20 within 24 hours

How long until the sample was frozen at -80?

   ◯ Frozen at -80 within 24 hours
   ◯ Frozen at -80 within 1 week
   ◯ Frozen at -80 within 2 weeks

What kind(s) of media were the samples stored in?

   ☐ Freeze
   ☐ RNA later
   ☐ Ethanol
   ☐ DNA Genotek

Was DNA isolated from the sample?

   ◯ Yes
   ◯ No

Where were samples obtained during the endoscopy or colonoscopy?

☐ Stomach Antrum inflamed
☐ Stomach Antrum uninflamed
☐ Stomach Corpus inflamed
☐ Stomach Corpus uninflamed
☐ Duodenum inflamed
☐ Duodenum uninflamed
☐ Terminal Ileum inflamed
☐ Terminal Ileum uninflamed
☐ Cecum inflamed
☐ Cecum uninflamed
☐ Right colon inflamed
☐ Right colon uninflamed
☐ Hepatic flexure inflamed
☐ Hepatic flexure uninflamed
☐ Transverse colon inflamed
☐ Transverse colon uninflamed
☐ Splenic flexure inflamed
☐ Splenic flexure uninflamed
☐ Left colon inflamed
☐ Left colon uninflamed
☐ Sigmoid colon inflamed
☐ Sigmoid colon uninflamed
☐ Rectum inflamed
☐ Rectum uninflamed
☐ Pouch inflamed
☐ Pouch uninflamed

What tissue locations were obtained from surgical resection?

☐ Ileum inflamed
☐ Ileum uninflamed
☐ Cecum inflamed
☐ Cecum uninflamed
☐ Right colon inflamed
☐ Right colon uninflamed
☐ Hepatic flexure inflamed
☐ Hepatic flexure uninflamed
☐ Transverse colon inflamed
☐ Transverse colon uninflamed
☐ Splenic flexure inflamed
☐ Splenic flexure uninflamed
☐ Left colon inflamed
☐ Left colon uninflamed
☐ Sigmoid colon inflamed
☐ Sigmoid colon uninflamed
☐ Rectum inflamed
☐ Rectum uninflamed
☐ Appendix inflamed
☐ Appendix uninflamed
(location of surgical resection samples)

Were the samples utilized immediately?

☐ Stored in the biorepository
☐ Given to Camilla
☐ Shipped to the Netherlands
☐ Given to Pfizer
☐ Given to a Snapper lab member
☐ Shipped to Stanford
☐ Other

Where were they shipped?   _____

Which lab member?   _____

Harvey Bradshaw Index
General wellbeing
- ◯ Very well (0)
- ◯ Slightly below par (1)
- ◯ Poor (2)
- ◯ Very poor (3)
- ◯ Terrible (4)

(Very well: no symptoms, except perhaps mild occasional bellyache or fatigue. (We can reference the ESR/CRP.))

HBI Abdominal pain
- ◯ None (0)
- ◯ Mild (1)
- ◯ Moderate (2)
- ◯ Severe (3)

HBI Number of liquid stools per day
_____

HBI Abdominal mass
- ◯ None (0)
- ◯ Dubious (1)
- ◯ Definite (2)
- ◯ Definite and Tender (3)

HBI Complications
- ◯ No
- ◯ Yes

Abscess?
- ◯ No
- ◯ Yes

Anal fissure?
- ◯ No
- ◯ Yes

Aphthous lesions?
- ◯ No
- ◯ Yes

Arthralgia?
- ◯ No
- ◯ Yes

Erythema nodosum?
- ◯ No
- ◯ Yes

New fistula?
- ◯ No
- ◯ Yes

Pyoderma gangrenosum?
- ◯ No
- ◯ Yes

Uveitis?
- ◯ No
- ◯ Yes

HBI total score
_____

SCCAI Bowel frequency (day)
- ◯ 1 to 3 (0)
- ◯ 4 to 6 (1)
- ◯ 7 to 9 (2)
- ◯ More than 9 (3)

SCCAI Bowel frequency (night)
- ◯ None (0)
- ◯ 1 to 3 (1)
- ◯ 4 to 6 (2)

SCCAI Urgency of defecation
- ◯ None (0)
- ◯ Hurry (1)
- ◯ Immediately (2)
- ◯ Incontinence (3)

SCCAI Blood in the stool
- ◯ None (0)
- ◯ Trace (1)
- ◯ Occasionally frank (2)
- ◯ Usually frank (3)

SCCAI General wellbeing
- ◯ Very well (0)
- ◯ Slightly below par (1)
- ◯ Poor (2)
- ◯ Very poor (3)
- ◯ Terrible (4)

Extraintestinal manifestations of IBD
- ◯ Yes
- ◯ No
(Check all that apply, 1 point each)

Arthralgia
- ◯ No
- ◯ Yes

Erythema nodosum
- ◯ No
- ◯ Yes

Pyoderma gangrenosum
- ◯ No
- ◯ Yes

Uveitis
- ◯ No
- ◯ Yes

SCCAI total score _____

PUCAI Abdominal pain
- ◯ None (0)
- ◯ Pain can be ignored (5)
- ◯ Pain cannot be ignored (10)
(All PUCAI items refer to the last week)

PUCAI Rectal bleeding
- ◯ None (0)
- ◯ Small amount only, in less than 50% of stools (10)
- ◯ Small amount with most stools (20)
- ◯ Large amount, >50% of stool content (30)

PUCAI Stool consistency
- ◯ Formed (0)
- ◯ Partially formed (5)
- ◯ Completely unformed (10)

PUCAI Stool frequency per day
- ◯ 0-2 (0)
- ◯ 3-5 (5)
- ◯ 6-8 (10)
- ◯ >8 (15)

PUCAI Nocturnal stools
- ◯ No (0)
- ◯ Yes (10)
(Did any nocturnal stools cause the patient to awaken?)

PUCAI Activity limitation
- ◯ No limitation of activity (0)
- ◯ Occasional limitation of activity (5)
- ◯ Severe restricted activity (10)

PUCAI Total score _____

Is the subject on any medications?
- ◯ Yes
- ◯ No

Aminosalicylate use within the last 2 weeks?
- ◯ Yes
- ◯ No

Which aminosalicylates are currently being used?
- ☐ Mesalamine (Asacol, Canasa, Pentasa, Rowasa, Apriso, Lialda)
- ☐ Balsalazide (Colazal)
- ☐ Sulfasalazine (Azulfidine)
- ☐ Olsalazine (Dipentum)

Antibiotic use within the last two weeks?
- ◯ Yes
- ◯ No

Which antibiotic(s)?
- ☐ Amoxicillin (Amoxil), Amoxicillin/Clavulanate (Augmentin)
- ☐ Ciprofloxacin (Cipro)
- ☐ Metronidazole (Flagyl)
- ☐ Rifaximin (Xifaxin)
- ☐ Trimethoprim/Sulfamethoxazole (Bactrim)
- ☐ Vancomycin
- ☐ Other

What antibiotic? _____

Probiotic use within the last month?
- ◯ Yes
- ◯ No

Which probiotic(s)?
- ☐ VSL3
- ☐ LGG (Culturelle)
- ☐ Florastor
- ☐ Other

What probiotic? _____

Glucocorticoid use within the last two weeks?
- ◯ Yes
- ◯ No

Which glucocorticoid(s)?
- ☐ Budesonide (Entocort)
- ☐ Hydrocortisone enema (Cortenema, Colocort, Cortifoam)
- ☐ Methylprednisolone (Solumedrol)
- ☐ Prednisone, prednisolone (Prelone)

Immunomodulator use within the last 3 months?
- ◯ Yes
- ◯ No

Which immunomodulator(s)?
- ☐ 6-mercaptopurine (6-MP)
- ☐ Azathioprine (Imuran)
- ☐ Methotrexate (Folex, Rheumatrex, Mexate)

Anti-TNF use within the last 3 months?
- ◯ Yes
- ◯ No

Which anti-TNF(s)?
- ☐ Infliximab (Remicade)
- ☐ Adalimumab (Humira)
- ☐ Certolizumab pegol (Cimzia)
- ☐ Golimumab (Simponi)

Calcineurin inhibitor use within the last three months?
- ◯ Yes
- ◯ No

Which calcineurin inhibitor(s)?
- ☐ Cyclosporine
- ☐ Tacrolimus

Other biologics within the last 3 months?
- ◯ Yes
- ◯ No

Which biologic(s)? ☐ Natalizumab (Tysabri)
☐ Ustekinumab (Stelara)
☐ Vedolizumab (Entyvio)

Has the subject received a fecal transplant? ○ Yes
○ No

Other meds within the last two weeks? ○ Yes
○ No

Which other medications? ☐ Thalidomide
☐ Other

What med(s)? _____

When were labs taken? _____

HCT (%) _____

WBC (K cells/uL) _____

PLT (K cells/uL) _____

CRP (mg/dL) _____

ESR (mm/hr) _____

ALB (g/dL) _____

Notes _____