**IBDMBD Clinical Research Coordinator SOPs**

Version: 2

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**NOTE:** References to all additional detailed protocol documents will be given in **Capitalized Bold Monospace Font**.

**Clinical Research Coordinator SOPs: Site coordinator tasks**

* Recruit an average of 2 patients per month per site.
* At each visit, perform medical record review and interview subject to complete source documents (screening, baseline, and follow up).
* On an ongoing basis, transcribe source documents (clinical metadata) into the study database, which will act as the Electronic Database Capture (EDC) for this study.
* At each visit, perform phlebotomy and process, label, and store labs as indicated.
* At each colonoscopy, process, label, and store biopsies as indicated.
* At each visit, assemble stool collection kits, and provide kits, instructions, and labels to subjects as indicated in the stool kit assembly instructions.
* At baseline visit, fill out stool collection calendar at time of enrollment for each subject. Make two copies, one to keep and one for the Broad project manager.
* On an ongoing basis, remind patients by email or phone call (on Fridays) when a stool sample and corresponding Activity Index and Dietary Recall is coming due.
* On an ongoing basis, if alerted that a sample is late, contact subject daily for 3 days and remind them to send their sample ASAP. If sample is not received by the end of the 3rd day (Friday), site investigator should be alerted to discuss terminating subject.
* On an ongoing basis, ship biospecimens as indicated in the SOPs (e.g. the Broad Institute, Wash U, Baylor Medical Center, Cedars-Sinai) in a timely manner.
* Compensate all subjects at the end of months 6 and 12 for stool collections and office visits completed to date. Stool collections should be compensated at the rate of $25 per sample for a total of $600 for 24 samples. Healthy controls will receive an additional $25 for each office visit including the colonoscopies.

**Clinical Research Coordinator SOPs: Recruitment (for new diagnosis)**

*For MLI, approach patient at time of scope as well but can have established diagnosis of IBD.*

**Scenarios:**

1. If imaging suggests ileal inflammation but cannot obtain ileal biopsies due to obstruction, can still enroll with serial stool samples (obtain biopsy of rectum at least and additional colonic site, if inflamed).
2. For all patients, obtain at least two ileal and two rectal biopsies, if possible, to place into RNALater. If inflammation is only in ileum, still obtain rectal biopsies. If predominant inflammation is in colon, obtain additional biopsy at site of inflammation in the colon (if outside of rectum).
3. All patients will have goal of at least two biopsy sites (rectum and ileum). This includes healthy controls.

**Clinical Research Coordinator SOPs: Schedule of Procedures**

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| **Table 1.** Procedures for diagnosed & suspected IBD subjects | **Screening** | **Baseline (visit 1)**  mo. 0 |  |  |  |  |  | **visit 2**  mo. 3  (+/- 2 weeks) |  |  |  |  |  | **visit 3**  mo. 6  (+/- 2 weeks) |  |  |  |  |  | **visit 4**  mo. 9  (+/- 2 weeks) |  |  |  |  |  | **visit 5**  mo. 12  (+/- 2 weeks) |
| **Week:** | NA | **0** | **2**2 | **4** | **6** | **8** | **10** | **12** | **14** | **16** | **18** | **20** | **22** | **24** | **26** | **28** | **30** | **32** | **34** | **36** | **38** | **40** | **42** | **44** | **46** | **48** |
| Biopsy Collection | X1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| SESCD | X1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Baron’s Score UC | X1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Screening source documents | X |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Baseline source documents |  | X |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Follow up source documents |  |  |  |  |  |  |  | X |  |  |  |  |  | X |  |  |  |  |  | X |  |  |  |  |  | X |
| Stool Collection |  | C1 | C2 | C3 | C4 | C5 | C6 | C7 | C8 | C9 | C10 | C11 | C12 | C13 | C14 | C15 | C16 | C17 | C18 | C19 | C20 | C21 | C22 | C23 | C24 |  |
| Activity Index & Dietary Recall Questionnaire CD and UC |  | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |  |
| Blood Collection (DNA) |  | X |  |  |  |  |  | X |  |  |  |  |  | X |  |  |  |  |  | X |  |  |  |  |  | X |
| Blood Collection (serum) |  | X |  |  |  |  |  | X |  |  |  |  |  | X |  |  |  |  |  | X |  |  |  |  |  | X |
| Blood collection for lab values (ESR & CRP) |  | X |  |  |  |  |  | X |  |  |  |  |  | X |  |  |  |  |  | X |  |  |  |  |  | X |
| HBICD |  | X |  |  |  |  |  | X |  |  |  |  |  | X |  |  |  |  |  | X |  |  |  |  |  | X |
| SCCAIUC |  | X |  |  |  |  |  | X |  |  |  |  |  | X |  |  |  |  |  | X |  |  |  |  |  | X |
| Patient Reported Symptoms Questionnaire  CD and UC |  | X |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| SIBDQ CD and UC |  | X |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| FFQ CD and UC |  | X |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Baseline Environmental Questionnaire CD and UC |  | X |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

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| **Table 2.**  Procedures for Healthy controls | **Screening** | **Baseline (visit 1)**  mo. 0 |  |  |  |  |  | **visit 2**  mo. 3  (+/- 2 weeks) |  |  |  |  |  | **visit 3**  mo. 6  (+/- 2 weeks) |  |  |  |  |  | **visit 4**  mo. 9  (+/- 2 weeks) |  |  |  |  |  | **visit 5**  mo. 12  (+/- 2 weeks) |
| **Week:** | NA | **0** | **2**2 | **4** | **6** | **8** | **10** | **12** | **14** | **16** | **18** | **20** | **22** | **24** | **26** | **28** | **30** | **32** | **34** | **36** | **38** | **40** | **42** | **44** | **46** | **48** |
| Biopsy Collection | X1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Screening source documents | X |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Baseline source documents |  | X |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Follow up source documents |  |  |  |  |  |  |  |  |  |  |  |  |  | X |  |  |  |  |  |  |  |  |  |  |  | X |
| Stool Collection |  | C1 | C2 | C3 | C4 | C5 | C6 | C7 | C8 | C9 | C10 | C11 | C12 | C13 | C14 | C15 | C16 | C17 | C18 | C19 | C20 | C21 | C22 | C23 | C24 |  |
| Activity Index  & Dietary Recall Questionnaire (controls to skip activity indices per instructions) |  | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |  |
| Blood Collection (DNA) |  | X |  |  |  |  |  |  |  |  |  |  |  | X |  |  |  |  |  |  |  |  |  |  |  | X |
| Blood Collection (serum) |  | X |  |  |  |  |  |  |  |  |  |  |  | X |  |  |  |  |  |  |  |  |  |  |  | X |
| FFQ |  | X |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Baseline Environmental Questionnaire |  | X |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1 Colonoscopy required at screening visit for enrollment. Additional colonoscopies only if clinically indicated.  2 stool samples should be received every two weeks +/- 1 week. | | | | | | | | | | | | | | | | | | | | | | | | | | |

**Clinical Research Coordinator SOPs:** **Coordinating the Screening, Baseline and**

**Follow up Site Visits**

**NOTE:** Each subject recruitment begins with a colonoscopy (the "screening colonoscopy"). If the subject is eligible and consents, the first visit (**Baseline Visit**) proceeds with additional study data collection and kit/instruction distribution. Subsequent visits by the subject to the clinic are considered **Follow Up Visits**, and some data is collected at *both* baseline and follow up (**Each Visit**). Finally, one additional colonoscopy may be performed as clinically indicated, with biopsy and data collection at *both* the screening and follow up colonoscopy (**Each Colonoscopy**).

**Screening colonoscopy**

Time: (Month 0)

1. All subjects (potential IBD patients as well as non-IBD controls) will undergo a screening colonoscopy with biopsy collection to determine eligibility.
2. Biopsies will be collected and processed as outlined in the Biopsy Collection and Storage SOP.
3. The **Simplified Endoscopic Score** (CD) and **Modified Baron’s Square** (UC) will be completed for suspected CD and UC subjects.
4. Coordinator will interview subject and perform medical record review to complete the **Screening Source Document** for every subject.

**Baseline visit**

Time: (Month 0)

*Data collection*

1. Proceed with the appropriate **Informed Consent** discussion for eligible IBD patients and non-IBD controls. If the subject agrees to participate in the longitudinal stool collections and study visits, have them sign longitudinal consent form approved for your site.
2. Complete either the Control or IBD **Baseline Source Document**.
3. For IBD patients, complete the **Short IBD Questionnaire** (SIBDQ).
4. For IBD patients, complete the **Patient Reported Symptoms Questionnaire**.
5. For IBD patients, complete the **Harvey Bradshaw Index** or **SCCAI** depending on disease.
6. Complete the **Baseline Environmental Questionnaire** (can optionally be completed at home and mailed back with first stool sample).
7. Complete the **Food Frequency Questionnaire** (can optionally be completed at home and mailed back with first stool sample).

*Sample collection*

1. Collect blood samples for DNA and serum and send separate blood tubes for ESR and CRP for standard of care.
2. Give subject first set of stool kits. This will contain enough supplies to last 3 months, or 6 collections.
3. Complete a **Stool Collection Calendar** for the subject and provide to them along with the **Instructions Stool** document.
4. Schedule follow up visit for no later than 3 months from baseline visit for IBD subjects and no later than 6 months from baseline visit for healthy controls.

**Follow Up Visits (2, 3, 4, and 5)**

Time: Months \*3, 6, \*9, and 12

\*IBD subjects only

1. Visits can occur within a +/- 2 week window.
2. Complete the **Follow Up Source Document**.
3. For IBD patients, complete the **Harvey Bradshaw Index** or **SCCAI** depending on disease.
4. Collect blood sample for RRBS (EDTA tube) and send separate tubes for ESR and CRP for standard of care.
5. Give patient next set of stool kits. This will contain enough supplies to last 3 months, or 6 collections. Stool kits can be mailed to healthy controls since they will not be visiting the site.
6. At months 3, 6, and 9, schedule next follow up visit for IBD subjects. At month 6 visit, schedule month 12 visit for healthy controls.

**Follow up colonoscopy (optional)**

Time: Approx. month 12 as clinically indicated

1. Biopsies will be collected and processed as outlined in the Biopsy Collection and Storage SOP.
2. The **Simplified Endoscopic Score** (CD) and **Modified Baron’s Square** (UC) will be completed for CD and UC subjects. Coordinator should record site of biopsy, number of biopsies and degree of inflammation per biopsy site on the screening colonoscopy source document.
3. Coordinator will interview subject and perform medical record review to complete the Screening colonoscopy source document for every subject.

**Clinical Research Coordinator SOPs: Identifying suspected IBD subjects and the screening colonoscopy/biopsy collection**

Step 1: Informed consent

IRB approvals will differ slightly between the three cohorts.

1. Subjects may initially sign the PRISM, Pediatric cohort, or MLI *disease control* consent form for the screening colonoscopy then sign the IBD Multi’omics consent form if their colonoscopy/ sigmoidoscopy results are consistent with IBD.

Note: Subjects would have to agree to at least 1 stool sample collection and research biopsies

1. All IBD Multi’omics procedures may be combined into a single consent form which would be signed prior to the screening colonoscopy. Subjects with colonoscopy/ sigmoidoscopy results not consistent with IBD would screen fail.

Step 2: Give the subject the C1 stool collection kit (including the ‘Activity Index and Dietary Recall’) to take home and instruct them to collect and mail their first sample [to the Broad] the day after their procedure.

Step 3: Collect research biopsies per Biopsy Collection and Storage SOP

Step 4: Once the pathology lab has confirmed the diagnosis (should be 24-48 hours), the study coordinator should contact the subject to:

* Review and sign the IBD Multi’omics consent form (if using method “A” above)
* Complete the baseline source documents
* Complete the baseline questionnaires
* Arrange for the subject to pick up or be mailed the remaining 5 stool collection kits (C2-C6).
* Schedule the month 3 follow-up visit

**Reminders:**

* Pediatric cohort and PRISM study teams should work with their practice and inpatient services to flag those patients coming in for a diagnostic colonoscopy for suspected IBD *in advance* whenever possible.
* For the MLI cohort, patients with a known diagnosis of IBD who have a colonoscopy scheduled for routine care can be asked to take part in the longitudinal study

**Clinical Research Coordinator SOPs: Identifying healthy controls and the screening colonoscopy/biopsy collection**

Step 1: Informed consent

Healthy controls undergoing a routine screening colonoscopy may be approached for participation. IRB approvals will differ slightly between the three cohorts.

1. Subjects may initially sign the PRISM, Pediatric cohort, or MLI *healthy control* consent form for the screening colonoscopy then sign the healthy control Multi’omics consent form.
2. All Multi’omics procedures may be combined into a single consent form for healthy controls, which would be signed prior to the screening colonoscopy.

Step 2: Give the subject the C1 stool collection kit (including the ‘Activity Index and Dietary Recall’) to take home and instruct them to collect and mail their first sample [to the Broad] 1-3 days following the procedure. Note: if completing the screening colonoscopy and baseline visit on the same day, subjects should be given stool collection kits C1-C6.

Step 3: Collect research biopsies per Biopsy Collection and Storage SOP

Step 4: The study coordinator should:

* Review and sign the healthy control Multi’omics consent form
* Complete the baseline source documents
* Complete the baseline questionnaires
* Arrange for the subject to pick up or be mailed the remaining 5 stool collection kits, C2-C6 (Only if the screening colonoscopy and baseline visits occur on different days)
* Schedule the month 6 follow-up visit

**Clinical Research Coordinator SOPs: Biopsy Collection and Storage at Each Colonoscopy**

**Locations:**

* In all adult subjects, collect the following research biopsies:
  + Between 3 and 5 from rectum (10cm)
  + Between 3 and 5 from ileum
* In all pediatric subjects, collect the following research biopsies:
  + Between 3 and 4 from rectum (10cm)
  + Between 3 and 4 from ileum
* Additionally, for suspected IBD subjects only (pediatric and adult), collect the following biopsies for DNA/RNA, *if possible*:
  + 2x from "other inflamed" region. If no inflamed tissue is available, collect only non-inflamed biopsies.
  + 2x from adjacent non-inflamed tissue.
* The maximum number of research biopsies collected will be 14 for adult IBD subjects and 10 for adult healthy controls. This is in addition to any biopsies taken for routine clinical care. The maximum number of research biopsies collected will be 12 for pediatric IBD subjects and 8 for pediatric healthy controls. This is in addition to any biopsies taken for routine clinical care.
* The minimum number of research biopsies to be taken is 6 for all subjects (2x DNA/RNA and 1x for histopathology from both the rectum and ileum). This is in addition to biopsies taken for routine clinical care.

**Processing:** Per site (Rectum/Ileum/Other Inflamed/non-inflamed):

***Important: Place ice packs in the freezer in advance of the biopsy collection so they are frozen in time for shipping.***

1. **Biopsy for histopathology**: send 1 biopsy for standard histopathology at individual institutions and record results on screening colonoscopy source document.

**B. Biopsies for RNA:**

1. Place 2 biopsies in separate RNAlater twist top 2mL storage tubes.
2. Place corresponding barcodes labels (**Labels Biopsies**) on storage tube and tracking form (**Tracking Form Blood And Biopsies**).
3. Record specimen on the subject's **Tracking Form Blood And Biopsies**.
4. Place tubes in a small bag and store in the refrigerator for 24 hours. After 24 hours, move to -20 freezer for long-term storage.
5. Ship biopsies overnight on dry ice to the Broad every 2 months.
6. **Biopsy for flora**:
7. Place 1 biopsy in sterile 2 mL tubes containing 5% glycerol.
8. Place corresponding barcodes (**Labels Biopsies**) on storage tube and tracking form (**Tracking Form Blood And Biopsies**).
9. Record specimen on the subject's **Tracking Form Blood And Biopsies**.
10. Place biopsies in -80 for long-term storage.
11. Ship biopsies overnight on dry ice every 2 months to the following contact:

MGH Crohn’s and Colitis Center

Attn: Holly Sturgeon

165 Cambridge Street

9th floor

Boston, MA 02114

**D. Biopsy for epithelial cell culture:**

1. See **Instructions Shipping Biopsy Culture**.
2. Record specimen on the subject's **Tracking Form Blood And Biopsies**.
3. Ship overnight surrounded by ice packs to Washington University:

Attn: Thad Stappenbeck & Kelli Vandussen

Washington University

4940 Parkview place

Pathology/CSRB room 1020

St. Louis, MO 63110

**Clinical Research Coordinator SOPs: Collecting, Aliquoting, and Storing Blood Samples at Each Visit**

\* denotes IBD subjects only

**DNA/ RRBS**

* Will occur at baseline visit and all follow up visits (months 0, \*3, 6, \*9, and 12)
* Draw blood into 3mL EDTA tube. Invert tube 8-10 times.
* Pipette 1 mL of whole blood (do not spin this tube) into Broad-provided tube for DNA/RRBS analysis.
* Place corresponding barcodes (**Labels Biopsies**) on storage tube and tracking form (**Tracking Form Blood And Biopsies**).
* Freeze tube (-20 or -80). If stored temporarily in -20, transfer to -80 within 48 hours.
* Record specimen on the subject's **Tracking Form Blood And Biopsies**.
* Send samples to the Broad for permanent storage and analysis every 2 months.

**Serum**

* Will occur at baseline visit and all follow up visits (months 0, **\***3, 6, **\***9, and 12)
* Draw blood into 5mL SST tube. Invert tube 8-10 times.
* Leave at room temperature for 40 minutes.
* Centrifuge for 15 minutes at 3,000rpm.
* Immediately aliquot 0.5mL into 2 mL microtubes. Fill as many tubes with 0.5mL as necessary.
* Place corresponding barcodes (**Labels Biopsies**) on storage tube and tracking form (**Tracking Form Blood And Biopsies**).
* Freeze tube (-20 or -80). If stored temporarily in -20, transfer to -80 within 48 hours

Note: DO **NOT** leave at room temperature overnight.

* Record specimen on the subject's **Tracking Form Blood And Biopsies**.
* Send one aliquot from each SST tube for serology every 2 months. Ship to the following contact:

Inflammatory Bowel Disease & Immunobiology Research Institute,

Cedars Sinai Medical Center

Attn: Michelle Li

110 George Burns Road

Davis RM 4094B

Los Angeles, CA 90048

* Send the remaining aliquots from each SST tube to MGH for storage every 2 months. Ship to the following contact:

MGH Crohn’s and Colitis Center

Attn: Holly Sturgeon

165 Cambridge Street

9th floor

Boston, MA 02114

**Clinical Research Coordinator SOPs: Broad Communication**

*This SOP describes regular communication and ongoing action items to be maintained between the Broad, the Clinical Site, and the patient with regard to stool sample collections.*

1. The site research coordinator(s) and/or site investigator(s) will be the only people to communicate directly with their subjects or receive any personally identifiable information.
2. At the time of each subject's enrollment, the coordinator will create tracking forms, **Tracking Form Stool** and **Tracking Form Blood And Biopsies** for recording each sample's collection and transport labeling and history. These forms will include no personal identifiers, only the subject ID and collection numbers (e.g. Subject 2001, Collection 1, 2, 3, etc.)

All future dates of collection will be filled in and should be scheduled to occur every other Monday until study completion. Two copies of each form will be made, one for the site coordinator and one for the Broad PM.

1. Subject identifiers are randomly assigned four-digit numbers that are unique to each subject.
   1. MGH/PRISM cohort will use ID’s 2001-2999.
   2. CSMC/MLI cohort will use ID’s 3001-3999.
   3. CCHMC pediatric cohort will use ID’s 4001-4999.
   4. Emory pediatric cohort will use ID’s 5001-5999.
2. The coordinator will create a schedule to call or email patients every Friday prior to the Monday that the stool specimen and questionnaires are due to be collected and shipped. If a patient prefers email or text message communication, reminders can be submitted in this fashion.
3. If a holiday is scheduled to occur on a Monday, advise patient to delay collection AND shipment until Tuesday.
4. The Broad PM will track which stool samples they expect to receive each day. At the end of the day they will call the appropriate site coordinator if any sample has not been received. Broad PM will continue to call the site coordinator at the end of every day until the sample is received.
5. If you are notified by the Broad PM that an expected sample was not received, contact the patient and remind them to ship the sample ASAP. Calls should continue on a daily basis until the sample is received.
6. Each research site coordinator will call the Broad every Thursday to discuss new enrollments and verify that all samples have been received by week’s end.
7. If a late sample has not be received by Friday of the week in which it was due (3 days late), please alert your site investigator to discuss terminating the subject.
8. If a patient reports a flare in disease activity, please request that they send their next stool sample as soon as possible (i.e. early) to best capture disease activity during the flare.

11. All blood, stool, and biopsy samples to be shipped to the Broad Institute:

Broad Institute

Biological Samples Platform (BSP)

301 Binney Street

Lab 5076

Cambridge, MA 02142

Ph: 617-714-8952

**Clinical Research Coordinator SOPs: Labeling & Shipping Biospecimens**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Sample Type** | **Sub-type** | **Labels** | **Label Process** | **Store or Ship?** | **Ship individually or batch?** | **Shipping Notes** | **Shipping Address & Contact** |
| Blood | DNA | LIMS | Coordinator to apply LIMS label immediately following blood draw | Ship to Broad | Batch & ship every 2 months | FedEx standard overnight with dry ice | Broad Institute  Biological Samples Platform (BSP)  301 Binney Street  Lab 5076  Cambridge, MA 02142 |
| Serum | Freezerworks | Coordinator to spin, aliquot & apply Freezerworks labels immediately following blood draw | Ship 1 aliquot to CSMC | Batch & ship every 2 months | FedEx standard overnight with dry ice | IBD & Immunology Research Institute  Cedars Sinai Medical Center  Attn: Michelle Li  110 George Burns Road  Davis Rm 4094B  Los Angeles, CA 90048 |
| Ship remaining aliquots to MGH | Batch & ship every 2 months | FedEx standard overnight with dry ice | MGH Crohn’s and Colitis Center  Attn: Holly Sturgeon  165 Cambridge Street  9th floor  Boston, MA 02114 |
| ESR/CRP | NA (clinical) | NA | NA | NA | NA | NA |
| Biopsies | Histopathology | NA (clinical) | NA | NA | NA | NA | NA |
| RNA/DNA | LIMS | Coordinator to apply LIMS label immediately following biopsy collection | Ship to Broad | Batch & ship every 2 months | FedEx standard overnight with dry ice | Broad Institute  Biological Samples Platform (BSP)  301 Binney Street  Lab 5076  Cambridge, MA 02142 |
| Flora | Freezerworks | Coordinator to apply Freezerworks label immediately following biopsy collection | Ship to MGH | Batch and ship every 2 months | FeEx standard overnight with dry ice | MGH Crohn’s and Colitis Center  Attn: Holly Sturgeon  165 Cambridge Street  9th floor  Boston, MA 02114 |
| Epithelial Cell Profiling \*excludes pediatric cohort | Freezerworks | Coordinator to apply Freezerworks label immediately following biopsy collection | Ship to  Wash U | Individually | FedEx priority overnight surrounded by ice packs (NOT dry ice!) | Washington University  Attn: Kelli VanDussen & Thad Stappenbeck  4940 Parkview Place  Pathology/CSRB room 1020  St. Louis, MO 63110 |
| Stool | Tube A  (w/ EtOH)  +  Tube B  (no EtOH) | LIMS | Coordinator to label tube A and tube B with LIMS labels before giving to patient | Patient to ship directly to Broad | Individually/ biweekly | FedEx std overnight; ambient  \*samples NOT to arrive on Sunday | Broad Institute  Biological Samples Platform (BSP)  301 Binney Street  Lab 5076  Cambridge, MA 02142 |

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| **Sample Type** | **Sub-type** | **Labels** | **Label Process** | **Store or Ship?** | **Ship individually or batch?** | **Shipping Notes** | **Shipping Address & Contact** |
| Tube A (with EtOH) | DNA/RNA  (2mL cryovial) | LIMS | BSP to apply LIMS aliquot label upon sample receipt | Store | NA | NA | NA |
|  | Mbx  (50mL conical tube) | LIMS | BSP to apply LIMS aliquot label upon sample receipt | Store | TBD |  | Clary Clish @ Broad |
|  | Viromics  (2mL cryovial) | LIMS | BSP to apply LIMS aliquot label upon sample receipt | Ship to BMC | Batches of 90 |  | Joe Petrosino @ Baylor Medical Center |
|  | Storage  (2mL cryovial) | LIMS | BSP to apply LIMS aliquot label upon sample receipt | Store | NA | NA | NA |
| Tube B (no EtOH) | Fecal Calprotectin  (15 mL conical) | LIMS | BSP to apply LIMS aliquot label upon sample receipt | Ship to MGH | Batches of 40 | FedEx standard overnight with dry ice | MGH Crohn’s and Colitis Center  Attn: Robin Wilson  165 Cambridge Street  9th floor  Boston, MA 02114 |
|  | Proteomics  (2mL cryovial) | LIMS | BSP to apply LIMS aliquot label upon sample receipt | Ship to LBNL | Batches of 8 | FedEx standard overnight with dry ice | Janet Jansson  Lawrence Berkley National Laboratory |