

# IBD Plexus Academic Request for Proposals (RFP)

## Program Guidelines and Policies

**Effective July 2020**

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**MISSION:**

*To cure Crohn's disease and ulcerative colitis, and to improve the quality of life of children and adults affected by these diseases.*

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## Key Dates

Activity	Date
<b>RFP published</b>	07/16/2020
<b>ProposalCENTRAL opens*</b>	08/17/2020
<b>Awards announced</b>	On a rolling basis
<b>Earliest start date</b>	November 2020

\* This is a rolling solicitation. The Foundation will continue to accept responses to the RFP until all awards are distributed.

## 1. Overview

The Crohn's & Colitis Foundation (Foundation) is excited to release a request for proposals (RFP) for academic researchers to gain access to IBD patients' biosamples and / or research-ready datasets housed within IBD Plexus. No funding will be provided through this RFP. Please see Section 5, Award Terms, for more details.

IBD Plexus<sup>®</sup> was founded by the Foundation to advance science, accelerate progress towards precision medicine and improve the care of patients living with IBD. The first-of-its kind, national-scale, cloud-based platform integrates clinical, patient-reported, genetic and other molecular data from diverse research study cohorts, real world clinical care settings and patients' experiences. IBD Plexus provides researchers with access to research-ready datasets to more rapidly perform activities that promise to speed treatment development, optimize existing therapies through development of biomarkers and diagnostics, and improve health outcomes. IBD Plexus unites clinicians, scientists, educators, industry partners, and patients to answer questions that are critically important to advance the field of IBD research.

The multi-component IBD Plexus includes a biobank, pediatric and adult patient clinical data, patient-reported data, biosamples, central reference labs to generate molecular data (genetic, transcriptomic, microbiomic, etc.), as well an analytical platform to house, organize, aggregate, and provide data for research.

The novel technological platform supports the mining of data for insights into IBD causes, mechanisms, biomarkers and potential new treatments. The "exchange" model functions under the guiding principle that researchers who take advantage of the resources will also contribute back the raw data (not the analyses) they derive from patient biosamples. As more stakeholders, including patients, clinicians, and researchers, contribute data, the IBD Plexus platform will evolve into an even more powerful database for future scientific research benefitting the entire IBD community.

## 2. IBD Plexus Cohorts

IBD Plexus centralizes and links data across diverse IBD research cohorts to facilitate sharing across the research community. The cohorts are all independent programs that have unique goals but the Foundation encourages clinicians and patients to participate in multiple cohorts, when applicable. IBD Plexus links the data and biosamples across these cohorts to create a robust individual patient dataset, enabling Plexus to achieve a comprehensive collection of holistic information to facilitate research and advance the scientific understanding of IBD.

This RFP provides the opportunity to gain access to biosamples and / or data from these study cohorts. Please click on the cohort hyperlink to learn more.

- **RISK** – A pediatric research study of newly diagnosed Crohn’s disease patients, designed to identify risk factors associated with developing penetrating and/or stricturing complications within 3 to 5 years of diagnosis (*Data sets and biosamples available – Table 1*)
- **SPARC IBD** – A translational research study that enrolls adult patients with Crohn’s disease and ulcerative colitis and follows them longitudinally to support the advancement of precision medicine (*Data sets and biosamples available – Table 1*)
- **IBD Qorus** – A longitudinally-followed adult quality of care program designed to drive progress towards improved care and health outcomes for patients living with IBD (*Data sets available – Table 1*)
- **IBD Partners** – An internet-based registry, open directly to patients, designed to better understand the patient view of the course of IBD and how patient experiences and unique IBD journeys impact disease course (*Data sets available – Table 1*)
- **SHP647 program** – Discontinued SHP647 program clinical trial data and biosamples will be made available to the scientific community through IBD Plexus. More details to come.

Patient-level data and biosamples collected from various cohorts include:

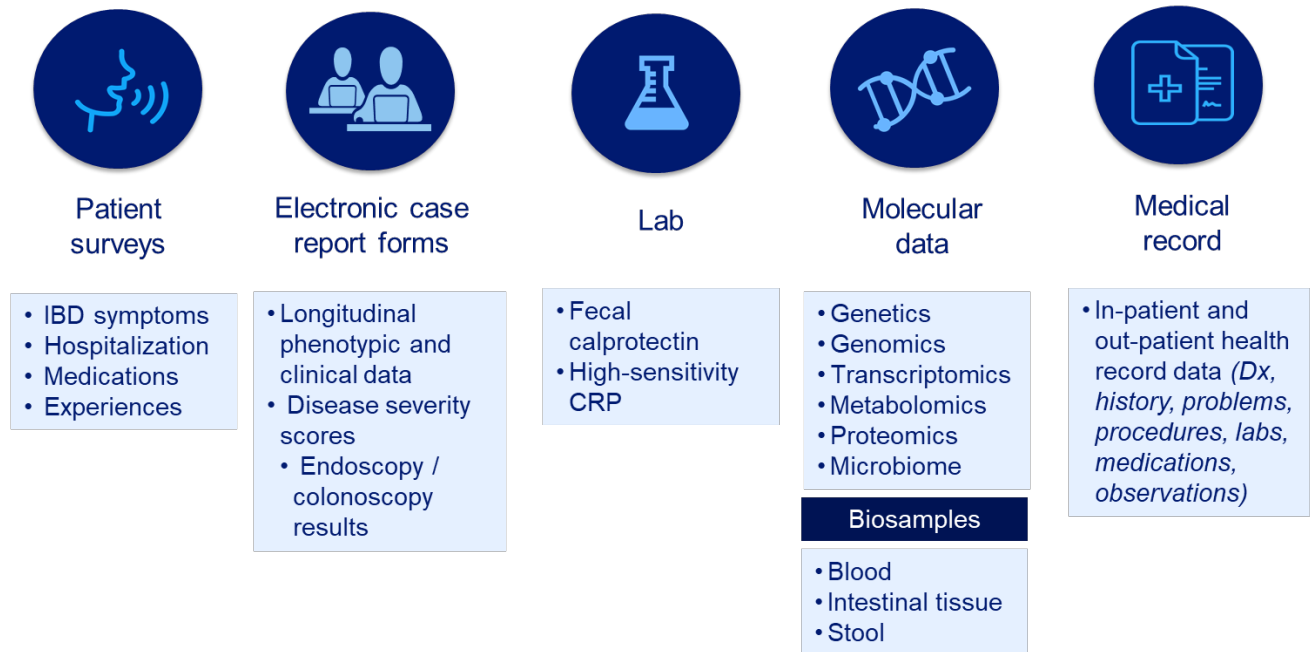


Table 1: Cohorts Data and Biosamples Collection Details

Cohort	Clinical Data	Patient Reported Data	Molecular Data	DNA	RNA	Plasma	PMBCs	Stool	Tissue Biopsies
SPARC IBD	✓	✓	✓	✓	✓	✓	✓	✓	✓
RISK	✓	✓	✓	✓	✓	✓		✓	✓
IBD Qorus	✓	✓							
IBD Partners		✓							

Note: More details to come for the SHP647 program data and biosamples.

Further details about the data collected in these cohorts can be found in the IBD Plexus Patient Data Specification document. This document is located in proposalCENTRAL within the Download Templates & Instructions section.

Table 2: Select clinical and demographic characteristics of IBD Plexus patients

Characteristics	RISK	SPARC IBD	IBD Qorus	IBD Partners
<b>Gender</b>				
Female	42%	55%	56%	72%
Male	58%	45%	44%	28%
<b>Age at enrollment</b>				
< 21	100%	24%	24%	4%
21 - 40	n/a	37%	35%	45%
41 - 60	n/a	30%	30%	38%
> 60	n/a	9%	11%	13%
<b>Diagnosis at enrollment</b>				
Crohn's Disease	63%	66%	57%	62%
Ulcerative Colitis	8%	32%	40%	35%
IBD-U	10%	2%	3%	2%
Not IBD	20%	n/a	n/a	n/a
<b>Medications (at any encounter)</b>				
5-ASAs	43%	25%	26%	48%
Antibiotics	35%	9%	6%	12%
Biologics	44%	71%	75%	44%
Immunomodulators	51%	32%	37%	33%
Steroid therapies	61%	16%	12%	30%
<b>Biologics breakdown</b>				
Adalimumab	13%	27%	12%	20%
Certolizumab	1%	3%	2%	5%
Golimumab	n/a	0.8%	1%	0.6%
Infliximab	40%	35%	48%	21%
Natalizumab	0.2%	0.1%	0.5%	0.9%
Ustekinumab	n/a	16%	8%	2%
Vedolizumab	n/a	19%	28%	5%

Table 3: IBD Plexus Molecular data

## Molecular data: SPARC IBD

Service	SPARC IBD		
	Samples	Patients	
Global screening array (genotyping)	2,950 blood DNA	Collection Time Period: Anytime CD: 1,949 UC: 948 IBD-U: 53	
Whole exome sequencing (genomics)	2,949 blood DNA	Collection Time Period: Anytime CD: 1,947 UC: 949 IBD-U: 53	
Immuno-sequencing (TCR profiling)	2,975 blood DNA	Collection Time Period: Anytime CD: 2,010 UC: 965	
Total RNAseq @ 50M reads (transcriptomics)	2,416 first event tissue 386 longitudinal tissue	Collection Time Period: First Event CD: 850 UC: 396 IBD-U: 34	Collection Time Period: Longitudinal CD: 134 UC: 71
FFPE H&E stained slides digitization	1,342 first event tissue 1,074 first event tissue 386 longitudinal tissue	Collection Time Period: First Event CD: 396 CD: 454 UC: 204 UC: 192 IBD-U: 14 IBD-U: 20	Collection Time Period: Longitudinal CD: 48 CD: 86 UC: 23 UC: 48
WGS - bacteria and fungi (metagenomics)	1,433 initial stool 367 longitudinal stool	Collection Time Period: Initial CD: 916 UC: 494 IBD-U: 24	Collection Time Period: Longitudinal CD: 150 UC: 103 IBD-U: 5
WGS viruses (metagenomics)	247 initial stool	Collection Time Period: Initial CD: 100 UC: 148	
Olink Explore 3072 (proteomics)	1,159 initial plasma 1,091 longitudinal plasma	Collection Time Period: Initial 1,159	Collection Time Period: Longitudinal 1,091

  Available Q3 2022

## Molecular data: RISK

Service	RISK	
	Samples	Patients
ImmunoChip (genotyping)	1,456 blood DNA	1,456
Global screening array (genotyping)	1,000 blood DNA	982
Protein expression (proteomics) 13 Olink Panels, 1196 proteins	250 plasma	250
RNAseq @ 10 M reads (transcriptomics)	778 (baseline tissue) 10 (longitudinal tissue)	565 10 (longitudinal)
RNAseq @ 30 M reads (transcriptomics)	850 baseline tissue 44 longitudinal tissue	567 29 (longitudinal)
RNAseq from FFPE slides	188 baseline FFPE slides 281 longitudinal FFPE slides 24 unknown timepoint FFPE slides	183 (baseline) 169 (longitudinal) 24 (unknown timepoint)
16S (rDNA sequencing)	888 tissue and stool	625
WGS - bacteria and fungi (metagenomics)	295 baseline stool	295
WGS viruses (metagenomics)	100 baseline stool	100
Methylation (epigenetics)	402 baseline and follow-up blood DNA	238

Table 4: IBD Plexus RISK Biosamples

RISK Biosamples			
Source	Sample Type	Time Point	Samples available details
Peripheral Blood	DNA	Enrollment, 1 year, 2 years and 3 years	DNA extracted
Peripheral Blood	Tempus™ RNA	Enrollment, 1 year, 2 years and 3 years	RNA extracted
Peripheral Blood	Plasma	Enrollment, 1 year, 2 years and 3 years	Stored -80C
<b>Stool</b>	Unprocessed	Enrollment	Aliquots stored -80C
Intestinal Tissue	RNAlater	Scope	RNA/DNA extracted

### **Periodicity of RISK Biosample Collection**

Baseline blood and stool samples were collected at / or around the time of enrollment. Follow-up blood samples were collected at year 1 and years 2 and 3. Mucosal biopsies are collected during routine colonoscopy as part of patient’s clinical care.

#### *Peripheral Blood*

Collected at the time of baseline, year 1, year 2, and year 3. Blood samples were used to isolate plasma, DNA and RNA, and thus whole blood samples or PBMCs are not available.

#### *Stool*

Fresh fecal samples were collected within 2 weeks of enrollment and flash frozen.

#### *Intestinal tissue biopsies*

Pinch biopsies were collected from Crohn’s disease patients during routine scheduled colonoscopies. 4 ileal and 4 rectal biopsy samples were collected in triplicate and stored in RNAlater.



Table 5: IBD Plexus SPARC IBD Biosamples

SPARC Biosamples			
Source	Sample Type	Time Point	Samples available details
Peripheral Blood	DNA	Baseline	DNA extracted
Peripheral Blood	Paxgene RNA	Baseline, Scope and 3 months after scope if change in therapies	Stored -80C
Peripheral Blood	PBMC's	Baseline, Scope and 3 months after scope if change in therapies	Aliquots of 5 million cells stored -80C
Peripheral Blood	Plasma	Baseline, Scope and 3 months after scope if change in therapies	Stored -80C
Stool	Nucleic Acid Archiving	Baseline, Scope and 3 months after scope if change in therapies	Stool in ethanol stored frozen
Stool	Unprocessed	Baseline, Scope, and 3 months after scope if change in therapies	faecal calprotectin generated + 6 aliquots unprocessed stored -80C
Intestinal Tissue (CD or UC or IBDU)	RNAlater	Scope	Stored -80C
Intestinal Tissue (CD or UC or IBDU)	Formalin	Scope	Paraffin embedded block
Intestinal Tissue (CD or UC or IBDU)	Flash Freeze (LN2)	Scope	Stored -80C

### **Periodicity of SPARC IBD Biosample Collection**

Biosamples are collected around the time of consent (blood and stool) and when the patient undergoes a sigmoidoscopy or colonoscopy as part of his or her clinical care. Blood and stool samples are also obtained approximately 3 months after a change in therapy that follows a colonoscopy or sigmoidoscopy if the patient has a follow-up office visit during that time.

#### *Peripheral Blood*

Collected at the time of enrollment, and used to isolate plasma, RNA and DNA. Additional samples are collected at the time of colonoscopy and 3 months after a colonoscopy if change in therapy where plasma, RNA, and PBMCs are isolated. These samples can be used for a variety of purposes including genotyping, transcriptomics, proteomics and metabolomics.

#### *Stool*

For baseline stool sample collection participants are provided with a stool kit at their first visit with instructions to collect the stool sample immediately after their visit. Participants collect the sample at home and ship cool whip container of preservative-free stool and an aliquot of stool stored in 95% alcohol to

preserve the sample for metabolomics. For the collection of stool at the time of colonoscopy, participants receive the stool kit 2 weeks prior the colonoscopy with instructions to collect samples preceding their bowel preparation. Preservative-free samples are sub-aliquoted upon arrival to the biobank and stored at -80°C. Stool samples are suitable for microbiomics, proteomics and metabolomics studies as well as for measurement of routine inflammatory markers such as fecal calprotectin.

#### *Intestinal tissue biopsy*

For patients with Crohn's disease undergoing colonoscopy up to 5 pinch biopsies are obtained using forceps from the ileum or the most proximal extent of the exam and the rectum (at 20 cm from the anal verge). If both the rectum and the ileum (or cecum) appear normal on insertion of the colonoscope, an additional 5 pinch biopsies are obtained from an area with macroscopically active disease, if present.

For those with ulcerative colitis or IBDU, up to 5 pinch biopsies are obtained from the cecum (or most proximal extent of the exam) and the rectum (at 20 cm). When there is not pancolitis, if feasible and safe, biopsies from the normal area just adjacent to the transition area from abnormal to normal appearing mucosa are obtained. If the only evidence of inflamed tissue on colonoscopy is located distal to 20 cm, the biopsies from the rectum are obtained more distally in the area of active inflammation.

For each anatomical region, biopsies are collected in RNAlater, snapped frozen at sites equipped with LN2, and collected in formalin and embedded into paraffin blocks at the biobank within 24hrs of collection.

### 3. Scope

The goal of IBD Plexus is to accelerate research in high impact areas. The Foundation seeks research proposals that would utilize IBD Plexus biosamples and / or data to drive progress towards precision medicine and / or leverage real world data to produce real world evidence. Priority will be given to proposals that enable answering one or more of the following main areas: 1) identification and / or validation of diagnostics / biomarkers, 2) therapeutic development and optimization 3) disease management 4) disease prevention

### 4. Eligibility

The lead principal investigator (PI) must be an investigator (e.g. Professor, Head of Research, Associate Professor, or equivalent) with expertise in a relevant field of research. At the time of application, PI and any co-PIs must be employed by an institution (public non-profit, private non-profit, or government) engaged in health care and/or health care related research. Proposals involving multiple institutions are welcome.

## 5. Award Terms

Up to forty-five (45) proposals will be selected for access to IBD Plexus biosamples and / or data for the term of the approved project proposal. The costs associated with the IBD Plexus data and biosample access fee is paid through funding from The Leona M. and Harry B. Helmsley Charitable Trust and Takeda Pharmaceutical Company Limited.

Investigators will have to pay for all costs associated with conversion of biosamples to molecular data performed at the IBD Plexus central reference laboratories (see section 7c for further information). Investigators who move to the proposal phase will be provided with project cost estimates.

Approved projects will require that the investigator / research site abides by the IBD Plexus data sharing guidelines, described in Section 8.

## 6. Submission Guidelines

LOIs and proposals should be submitted to proposalCENTRAL at:  
<https://proposalcentral.com>

To submit a LOI / proposal follow the steps below:

1. Define a research question that addresses areas of priority interest described in Section 3 of this RFP.
2. Submit an LOI through proposalCENTRAL.

To submit your proposal, applicants must have created or need to create an account in proposalCENTRAL.

- If you are a first-time user, navigate to <https://proposalcentral.com> and register by clicking on “First time user.” This will generate a confirmation number which will be emailed to the email connected to this account. Confirm your registration by submitting this number when prompted.
- If you have already registered to proposalCENTRAL, enter your username and password and submit.

After login in, click on “Grant opportunities” on the far right of the page and select “Crohn’s & Colitis Foundation” under ‘Filter by Grant Maker’ drop down menu on the upper left of the page.

Locate “IBD Plexus” announcement and click “Apply now” to submit a LOI.

The LOI is mandatory for all applications and will be considered seriously. Not all LOIs will be accepted for full proposal. LOIs with missing fields will not be approved.

The LOI will include:

- Project title (do not use abbreviations unless absolutely necessary)
- Request type (select the type of request) and enter additional request type in the free text field if more than one type of request is submitted
- Applicant/PI information
- Institution information
- Funding Source (required only if applying to access biosamples)

Note: Any funding from industry for this RFP must come from an IBD Plexus Industry member or be limited to investigator-initiated sponsored research agreements where the PI receives the data/biosamples and does not share the underlying or resulting data or biosamples with the industry supporter earlier than, or in any fashion that is more detailed than, what is publicly disclosed to the scientific research community.

#### Abstract

- **Scientific Summary of the Project (400 words)**  
The Scientific Summary should provide a clear, concise overview of the proposed work, including the background, objective, or hypothesis and its supporting rationale; specific aims of the study for the general scientific audience.
- **IBD Plexus Usage Rationale (250 words)**  
The rationale should include why your project should use IBD Plexus resources and how it will further both research and IBD Plexus mission.

Note: Since no consultations are offered at time of LOI submission, LOIs will be evaluated for concept. If LOI moves onto proposal stage, you have the opportunity to set up a consultation with the IBD Plexus team.

3. After the LOI is submitted, if the LOI is approved, you will receive an email notification from proposalCENTRAL to submit a full proposal.

Arrange a free one-on-one consultation with the IBD Plexus Research team or one of the PIs of an IBD Plexus cohort to help develop your proposal. Researchers are encouraged to seek support for proposal development and submission from one of the cohort's investigators, which may include a one-on-one consultation to discuss the proposal in advance of the submission. The purpose of the consultation is to guide understanding of the IBD Plexus data and biosamples in order to submit a well-informed proposal to streamline the submission / review process.

4. The following documents will need to be attached to your full proposal within proposalCENTRAL:
- Proposal title
  - Select the Challenges in IBD priority area that is addressed by the proposal. Please find [link](#) to *Challenges in IBD* manuscript.
  - A cover letter stating the overall purpose and rationale of the proposed research study.
  - NIH format biosketch or / CV of the PI and key personnel
  - Relevance of the proposal to IBD Plexus' mission. Provide a rationale for the use of IBD Plexus resources and explain how this study will further both IBD Plexus and Foundation's respective missions.
  - A study proposal, not to exceed 6 single-spaced pages, that provides the hypothesis, specific aims, rationale, design, and analysis plan for the data and/or biosamples, including a general statement of project impact to advance IBD is required.
  - Bibliography
  - Lay summary. Lay patients and caregivers participate as voting members of the IBD Plexus Project Selection Committee. The lay summary should be a clear, concise overview in simplified language, appropriate for non-scientific reviewers. You need to provide enough essential information that the lay reviewers are able to evaluate your application. The lay summary should include the following information:
    - What question will this project attempt to answer?
    - Why is this question important to IBD?
    - What is the study design?
    - How do the hypothesis and specific aims fit with IBD Plexus and Foundation's priorities?
    - Will this research project, if successful, further IBD Plexus' mission to accelerate progress toward precision medicine and improve quality of life for IBD patients? If so, how will this project do so?
  - Face sheet signed by institutional officer acknowledging agreement with award policies
  - Statement regarding source (e.g. industry sponsored) / availability of funds for project

**Note:** Additional details may be requested from the investigators based on the initial review by the IBD Plexus Project Selection Committee.

**Note:** Titles and lay summaries of your Letter of Intent and your full proposal will become public information and will be shared in a public domain. Therefore, please do not post a title or lay summary that includes proprietary/confidential information.

## 7. Application Review

### a. IBD Plexus Project Selection Committee

The IBD Project Selection Committee is charged with evaluating proposals. It makes decisions to approve, revise and resubmit, or deny proposals, and will monitor use of resources, help regulate and prevent duplicative projects, and encourage collaboration, where appropriate.

The Project Selection Committee is comprised of:

- Chair (*Independent Adult IBD Scientist*)
- Co-Chair (*Independent Pediatric IBD Scientist*)
- A subset of researchers from each cohort (*SPARC IBD, RISK, IBD Qorus and IBD Partners*)
- A biostatistician
- Independent researchers (*not affiliated with any cohort*)
- Patient(s) and caregiver(s)

Project Selection Committee members are subject to the Foundation's conflict of interest policies. Members are required to remove themselves from any reviews and/or discussion that could pose a conflict of interest as defined by Foundation's Peer Review Integrity Policy.

### b. Proposal Review Criteria

Proposals will be reviewed against criteria including:

- Impact / priority
- Significance to IBD
- Innovation
- Approach
- Investigator
- Quality of research environment
- Value to IBD Plexus and the broader scientific community

Members of the IBD Plexus Project Selection committee will evaluate and rate each proposal using the scorecard in Appendix 1.

### c. [Biosamples request](#)

For proposals requesting biosamples access, additional criteria will be evaluated:

- Rationale of biosamples request
- Size of request for biosamples (sample size should be appropriate for the research aims)
- Laboratory proposed for the biosamples analysis\*

\*IBD Plexus has selected central reference laboratories to ensure standardization across technology, standard operating procedures (SOPs) and assays, and to reduce other variables that affect test results and uniformity. Each central reference lab is a leading contract research organization (CRO) in one or more of the following:

- Microbiome
- Genomics
- Transcriptomics
- Metabolomics
- Proteomics

We require all biosamples be sent to our central reference labs for data generation unless there is a necessary exception such as a proprietary assay.

**It is highly recommended that researchers consult with the IBD Plexus Research Team prior to submit a proposal.** All proposals requesting biosamples will be vetted by an independent biostatistician to ensure the proposed biosamples size is sufficiently powered (and not excessive) to test the proposal's hypotheses.

### d. [IRB approval](#)

If a proposal includes a request for the use of a Limited Data Set, as defined by HIPAA (including in connection with a proposal requesting biosamples), researcher must obtain IRB approval prior to receiving access to the Limited Data Set. Please note that IRB approval can come after proposal submission and approval however data release is contingent on IRB approval.

### e. [Conflict of Interest](#)

The Crohn's & Colitis Foundation seeks excellence in the discovery and dissemination of knowledge regarding the cause, prevention, detection and diagnosis, treatment, survivorship and health policy of Crohn's disease and ulcerative colitis, collectively known as inflammatory bowel diseases (IBD). This requires that all individuals affiliated with, or funded by, the Crohn's & Colitis Foundation adhere to the highest standards of professional integrity. Volunteer grant reviewers for the Crohn's & Colitis Foundation will also be held to the highest codes of conduct and integrity in performing their essential function of peer review. Please reference our [Guidelines for Maintaining Research and Peer Review Integrity](#) for details.

## 8. Data Sharing - Targeted / Non-Targeted Data

At the time of proposal review, the Project Selection Committee will determine whether it approves the Proposal as a Targeted Project or Non-Targeted Project as defined below.

Two exclusivity periods have been defined based on data type. Non-targeted data derived from biosamples is not considered competitive knowledge while targeted derived data can potentially contain competitive knowledge due to the insights that could be gleaned from the data. Please see definitions below.

- **Non-targeted data**

*Definition: Generated data that is not directed at a particular hypothesis but rather is a preliminary exploration of the data. (e.g., unbiased RNA sequencing)*

- Generation of non-targeted data, whenever possible, should be generated at an IBD Plexus designated central reference laboratory. In select cases for which an IBD Plexus designated central reference laboratory does not have the capability to generate non-targeted data, IBD Plexus will approve receipt by recipient of samples so that recipient may generate non-targeted data.
- If the project generates non-targeted data, the researcher must deposit raw data generated into the IBD Plexus platform as per whichever milestone below is reached first
  - 180 days (6 months) after recipient's last receipt of resources
  - Acceptance of a project manuscript for publication

- **Targeted data**

*Definition: a) Data that has been generated to answer a focused hypothesis (e.g., association between three thiopurine metabolites and mucosal healing in patients with Crohn's disease) b) Data that has been generated using a non-commercially available assay*

- If the project generates targeted data, the researcher must deposit data generated into the IBD Plexus solution as per whichever milestone below is reached first
  - 540 days (18 months) after recipient's last receipt of resources
  - Acceptance of a project manuscript for publication
  - Recipient's filing of a patent application
- Researchers can submit a request for an extension as long as there has been adequate progress of the research toward publication or patent filing as determined by the Project Selection Committee.
  - Extension requests must be submitted by month 14
  - Extensions will be capped at one additional year of data exclusivity



## 9. Duplicate or overlapping proposals

For proposals found by the Project Selection Committee to have overlapping project scopes, the Project Selection Committee will assess the degree of overlap with existing projects as part of the review process. If more than one researcher is requesting the same biosample(s) to generate the same data, a member of the Project Selection Committee will notify the researcher that there is a project that has an overlapping request. Note: No confidential information will be shared. If there is substantial overlap, an effort will be made to encourage collaboration without revealing the identity of the researchers.

1. If the researchers agree to collaborate, then they will jointly share ownership of and exclusivity rights in and to the project analyses and biosample-derived data. The researchers will agree on how to allocate costs associated with the Proposal between them.
2. If the researchers do not agree to collaborate, the Project Selection Committee will rank the overlapping proposals based on which proposal is based on the best science and will approve one researcher's proposal and deny the other Researcher's proposal.
3. In cases where the scientific merit of the overlapping proposals is equal (or similar), the biostatistician will help the Project Selection Committee determine appropriate division of biosamples between the two researchers, and the biosamples will be apportioned accordingly.

## 10. Request fulfillment

Once a proposal is approved, researchers will work with the Foundation to gain access to the approved biosamples and /or data.

### Data fulfillment

Researchers must abide by the IBD Plexus data use agreement which states that data cannot be used for non-permitted commercial use, or the use of data for product promotion, marketing, targeting segments of the physician IBD landscape to understand prescribing patterns or re-identifying patients, or any other uses that the Foundation Ethics Committee deems as unethical.

### Biosamples fulfillment

The Foundation will provide requested biosamples along with a Material and Data Transfer Agreement (“**MDTA**”) See Appendix 3, which sets forth the terms and conditions governing operational matters including shipment of biosamples, applicable additional costs and protocol for conducting the proposed analyses.

If biosamples are sent to one of the Foundation's IBD Plexus central reference labs, the Foundation will provide the researcher with the biosample-derived data relating to such biosamples. If biosamples are sent to a non-Foundation central

reference lab, the researcher must provide the Foundation with all biosample-derived data relating to such biosamples as per the targeted / non-targeted data requirements.

## 11. Publication requirements

Within thirty (30) days after creation of the final draft of any paper analyzing or otherwise utilizing Data and prior to its submission for publication (each manuscript, a “Project Paper”), PI shall provide the IBD Plexus Publication Review Committee with a copy. PI shall use best efforts to seek publication of any Project Paper in accordance with generally accepted scientific standards.

Project Papers will be reviewed by a subset of the Publication Review Committee on an ad hoc basis, provided that such review shall not exceed thirty (30) days from receipt of the Project Paper by such Committee. If there are no concerns with publication, then PI may move forward with publication efforts; however, if review of the manuscript indicates that issues need to be addressed, then the Project Paper will be reviewed by the entire Publication Review Committee, provided that such review shall not exceed sixty (60) days from receipt of the Project Paper by such Committee. Reasons for additional review include, but are not limited to, the following:

- Manuscript contains one or more egregious methodological errors
- Manuscript generates major reviewer concerns regarding methodology, findings and/or conclusions that are found to misinterpret the data and/or cohorts
- Manuscript is market research analysis
- Manuscript falls outside the scope of the approved Project

In the event that the Publication Review Committee provides comments to the PI, PI shall consider such comments.

Foundation may make any Project Paper available through IBD Plexus after its publication, provided that it is permissible by the publishing journal and doing so does not compromise the publishability of any Project Paper.

Any Project Paper shall include written acknowledgement of the Foundation: e.g., “The results published here are in whole or part based on data obtained from the IBD Plexus program of the Crohn’s & Colitis Foundation.”

The Foundation acknowledges that researchers with access to IBD Plexus resources may be required by third parties to provide copies of data they use in research projects for the purposes of validating or reproducing research results, for example, in order to publish their results in a journal, or because they are subject to other data sharing requirements, for example, because they receive funding from the U.S. government.

This Policy sets forth the Foundation’s commitment to support these researchers in fulfilling their commitments to third parties by allowing for the use of

IBD Plexus data resources for validation, reproducibility, data sharing or other legitimate purposes.

The Foundation will use the following procedures to allow for access to IBD Plexus data as discussed in this Policy:

A researcher with access to IBD Plexus resources will notify the Foundation in writing promptly upon becoming aware that the researcher is subject to a requirement described in this Policy, including identification of the IBD Plexus data that is subject to this requirement, a description of the requirement, and the third party that imposes this requirement, as follows: [name and email address]. If the circumstances are such that the researcher cannot provide this notice, then the entity requiring access to the IBD Plexus data may provide this information to the Foundation.

The Foundation will cooperate in good faith to make available the IBD Plexus data that must be accessed for a purpose set forth in this Policy. Ordinarily, this will mean that a particular third-party researcher or research team will be given access to IBD Plexus data through execution of a data use agreement with a researcher or research team for access to the IBD Plexus data only for the purpose of validating or reproducing the results as required by a journal policy, data sharing requirement, or other legitimate purpose. The Foundation may require other reasonable terms and conditions in return for providing access to IBD Plexus data, such as: that the third party researcher or research team not use the data for any purpose other than validation or reproduction of the research results, and that the data and all copies be securely stored so that the data is not used for any other purpose, and/or returned or destroyed.

In the event that a researcher with access to IBD Plexus data is subject to a requirement by a third party for which a data use agreement and provision of the data by the Foundation directly to a researcher or research team as set forth above is not sufficient, for example, if a U.S. government data sharing policy to which the researcher is subject requires deposit of a data set into a non IBD Plexus repository, then the Foundation will cooperate in good faith to allow that researcher to discharge his or her obligations with respect to that requirement.

Ordinarily, the Foundation will agree to allow a researcher who is subject to a requirement to deposit IBD Plexus data into a non IBD Plexus repository on the following conditions: (a) the researcher informs the Foundation in writing promptly upon learning that he or she is subject to such a requirement (and ideally at the time that the researcher submits a request to IBD Plexus for IBD Plexus data) and allows the Foundation the opportunity to ensure that such deposition requirement will include the license features set forth in Section 4(b) of this Policy and will not violate Section 5 of this Policy; and (b) the Foundation will approve deposition of IBD Plexus data provided that the researcher deposits such data subject to a Creative Commons license with all of the Attribution (including identification of IBD Plexus as a source of the IBD Plexus data), Non Commercial and Share Alike features or their equivalent.

With respect to all of the foregoing in this Policy, the Foundation reserves its rights to, at its discretion, manage IBD Plexus so that the Foundation's obligations to third parties are not violated or otherwise compromised in its efforts to support researchers in fulfilling their responsibilities with respect to journal publication requirements, receipt of U.S. government funding and other requirements.

## APPENDIX

### Appendix 1 – IBD Plexus Project Selection Review Criteria

## IBD Plexus Project Selection Review Criteria

Please provide prose or bullet points of the strengths and weaknesses, and use the scale, referenced at the bottom of this page, to score from 1-9 (1 = exceptional, 9 = poor) for each section.

REVIEWER:

INVESTIGATOR:

PROPOSAL TITLE:

DATE:

#### Score

**OVERALL IMPACT/PRIORITY:** Give an overall score based on all of the review criteria and overall scientific merit. If Academic proposal, particularly consider the likelihood that the proposal will position the applicant for additional funding (e.g., NIH grant). The impact / priority must align with the Foundation's Challenges in IBD five focus areas: precision medicine, pragmatic / clinical research, preclinical human IBD mechanisms, novel technologies and environmental triggers. The impact / priority must also align with the scope of this RFP as described in section 3.

#### Score

**SIGNIFICANCE:** Does the proposal address a significant knowledge gap in basic or clinical understanding of IBD or related gastrointestinal diseases? Is the proposal likely to lead to significant gains?

#### Score

**INNOVATION:** Does the application propose novel concepts, approaches or methodologies, aimed at improved bench to bedside research in IBD and driving progress to precision medicine or improving the overall health of patients with IBD? Assess the translatability of the proposal.

#### Score

**APPROACH:** Include a comment on whether the proposed work is appropriate in scope and the methods are feasible.

**Score**

**INVESTIGATOR(S):** *Is this an experienced investigator with a track record of high quality productivity and collaboration in the field? If a non-IBD investigator, proposal needs to include at least one co-investigator with IBD experience. If a junior investigator, do they have a mentor/mentoring team with the appropriate qualifications to supervise the work? (NIH Biosketch to be reviewed for Academic researchers and NIH Biosketch or work experience section to be reviewed for Industry researchers)*

**Score**

**ENVIRONMENT:** *Comment on the IBD Plexus resources that will be used: data and biosamples. Is the investigator in the right environment to make optimal use of the IBD Plexus resources?*

**Score**

**VALUE TO THE NETWORK:** *Will this project add new data into the IBD Plexus platform? If so, are the new resources created following IBD Plexus standards and useful to the research community?*

**Is the researcher requesting biosamples?** Yes  No

*Projects which will utilize biosamples will need to receive an outstanding impact score and have a high likelihood of success. **Careful attention will be paid to the amount of the biosample requested.***

If yes, please fill out the additional review criteria

**Score**

**BIOSAMPLE USAGE:** *Does the rationale of the study justify use of the requested samples? Is the number of samples requested reasonable and sufficiently powered to achieve statistical significance? Type of biosample (tissue, blood, stool)*

**Score**

**LAB VENDOR:** *Is the investigator using IBD Plexus reference lab? If not, is the lab that the investigator is proposing to use for molecular analysis considered high quality? Is the lab willing to provide the necessary metadata back to IBD Plexus and*

also provide the data back in a format that can be easily migrated into IBD Plexus? Does this proposal merit use of an outside lab?

**Please use the following 1-9 scoring scale**

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses
<p><b>Minor Weakness:</b> An easily addressable weakness that does not substantially lessen impact  <b>Moderate Weakness:</b> A weakness that lessens impact  <b>Major Weakness:</b> A weakness that severely limits impact</p>			

## Appendix 2 – IBD Plexus Data Use Agreement

This Data Use Agreement (“Agreement”) is by and between the Crohn’s & Colitis Foundation (“Foundation”), a non-profit tax exempt organization pursuant to Section 501(c)(3) of the Internal Revenue Code, with an address at 733 Third Avenue, Suite 510, New York, NY 10017 and XXX (“Site”), with offices at XXX. Foundation and Site each may be referred to herein as a “Party” or collectively as the “Parties” to this Agreement.

### Recitals

Foundation administers IBD Plexus, a resource for scientific researchers which includes patient data and information, that was created to accelerate research, drive progress toward precision medicine, and transform the care of patients living with Inflammatory Bowel Diseases (“IBD”).

Site employs XXX (the “Principal Investigator” or “PI”), an IBD researcher approved by the IBD Plexus Project Selection Committee (“PSC”) to receive IBD Plexus data.

Foundation and Site agree that PI shall receive access to certain IBD Plexus data on the terms and conditions of this Agreement.

### Agreements

For good and valuable consideration, the sufficiency of which is acknowledged, the Parties agree as follows:

**1. Data.** PI shall receive the data (“Data”) identified for the purpose of conducting the project set forth in the PSC approved research proposal attached as Exhibit A (the “Approved Project”). PI may request additional use of the Data but no such additional use shall occur without prior written permission of Foundation and, upon such written permission such additional use shall be an Approved Project.

(a) Transfer/Disclosure of Data. The Data shall not be transferred to anyone not working on the Project without the prior written permission of Foundation, provided that nothing herein shall prevent Site from meeting its obligations pursuant to any applicable law, or PI from meeting any obligation requiring the Data to be made available in connection with publication of the results of the Approved Project.

(b) Subject PHI. PI shall receive a deidentified data set. Neither Site nor PI shall be permitted to use such information to re-identify the individuals nor to contact them under any circumstances. In the event PI receives protected health information or information that is otherwise protected by any applicable law (any of the foregoing, “Subject PHI”), then PI shall not use such information to identify any individual nor contact them under any circumstances, shall only use such Subject PHI in accordance with applicable law, and PI shall return or destroy upon Foundation’s written request and option, or, if PI requests in writing and Foundation agrees that return or destruction is not feasible under the circumstances, then Site shall retain such information under these terms and conditions.



**2 Storage and Access to/Use of Data.** Site shall safeguard storage of the Data and prevent its use or disclosure in violation of this Agreement. Only the PI, and individuals under the PI's supervision, will have access to and use the Data.

**3 Compliance; Notice of Withdrawal.** PI shall use the Data in compliance with all applicable laws. Site and PI are responsible for obtaining and adhering to any Institutional Review Board ("IRB") approvals necessary to perform the Approved Project. If Site receives written notice from Foundation that a patient, as identified using the unique coded identifier, whose Data has been provided, wishes to withdraw permission for use of such Data (a "Notice of Withdrawal"), then PI only shall use such Data to the extent necessary to protect the integrity of the Project.

**4 Notifications of Breaches and Security Incidents.** Site shall notify Foundation in writing as soon as possible, but in no event more than three (3) calendar days, after becoming aware of any breach or, or security incident involving, Subject PHI. Site shall be deemed to be aware of any breach or security incident as of the first day on which such breach or security incident is known to any of its officers or employees. Site shall identify as soon as practicable each individual whose Subject PHI has been, or is reasonably believed to have been accessed, acquired, or disclosed during such breach or security incident. Site shall cooperate in good faith, at its own cost and expense, in the investigation by Foundation of any breach or security incident.

(a) Prompt Corrective Actions. Site shall: (i) take prompt corrective action to remedy any breach or security incident, and (ii) mitigate, to the extent practicable, any harmful effect of a use or disclosure of Subject PHI in violation of this Agreement.

(b) Notification of Corrective Action and Provision of Policies. Site will provide written notice as soon as possible but no later than ten (10) calendar days from the date that Site provided notice to Foundation, of: (i) the actions taken by Site to mitigate any harmful effect of such breach or security incident; and (ii) the corrective action Site has taken or shall take to prevent future similar breaches or security incidents. Upon Foundation's request, Site will also provide to Foundation a copy of Site's policies and procedures for handling patient information or information security.

**5 Intellectual Property Rights ("IPRs"); New data/information; New Resources.**

(a) Claim of IPRs. Site and/or PI may claim IPRs on inventions or discoveries involving use of the Data provided that Site and PI shall not claim any IPRs or any ownership rights, or permit any claim or assertion of IPRs or ownership rights, in any of or any part of, the Data.

(b) Non-Targeted Data. If the Approved Project generates analyzed or interpreted Approved Project data ("Project Results") not directed at a particular hypothesis, but rather is a preliminary exploration of the data ("Non Targeted Data"), then,

with respect to such Non-Targeted Data, upon the earlier of: (a) one hundred eighty (180) days after the last grant of Data to PI; (b) acceptance of an Approved Project manuscript for publication; or, (c) filing of a patent application, Site shall provide to Foundation in writing: (i) information about the status of the Approved Project, including identification of any New Resource (defined in Subsection (d)); and (ii) new raw Approved Project data in a manner that retains linkage of such data to the Data, which new raw Approved Project data may be released to third party researchers in connection with new research projects.

(c) Targeted Data. If the Approved Project generates Project Results directed at one or more particular hypotheses (“Targeted Data”), then, with respect to such Targeted Data, upon the earlier of: (a) five hundred forty (540) days after the last grant of Data to PI; (b) acceptance of an Approved Project manuscript for publication; or, (c) filing of a patent application, Site shall provide to Foundation in writing: (i) information about the status of the Approved Project, including any New Resource; and, (ii) new raw Approved Project data in a manner that retains linkage of such data to the Data, which new raw Approved Project data may be released in connection with new research projects.

(d) New Resources. If PI and/or Site creates any novel resources (which shall include new data, information and results) useful to scientific researchers that arise from use of the Data, including without limitation that may be protectible as an IPR (“New Resources”), then Site shall notify Foundation and, if requested by Foundation, provide a copy of all such New Resources to Foundation at cost and without markup, for at cost distribution to scientists performing research into the causes of and cures for IBD, and provided that (i) any New Resource that is not new raw Approved Project data that may be commercializable by Site only shall be made available by Foundation to non-commercial organizations, (ii) this sublicensable license shall be subject to Sections 5(b) and (c), (iii) such distribution will not grant to any third party any other right to such New Resources; and (iv) any recipient of such New Resources shall agree to substantially similar terms and conditions as the ones set forth in this Agreement, including without limitation release and indemnification of Site and PI as contributor for receipt, storage and use of any New Resource.

**6. Reporting Requirements.** PI and/or Site is required to submit an annual progress report for the Approved Project, which will be reviewed by the members of the National Scientific Advisory Committee or Foundation staff.

**7. Notice.** Any notice required or permitted by this Agreement shall be made by one Party to the other Party as follows:

to Foundation:

Justine Young  
Manager, Business & Research Ops  
Crohn’s & Colitis Foundation  
733 Third Avenue, Suite 510  
New York, NY 10017  
E: [jyoung@crohnscolitisfoundation.org](mailto:jyoung@crohnscolitisfoundation.org)  
T: (646) 965-2270

to Site:

**7. Press and Publication.**

EFFECTIVE DATE: JULY 2022

(b) The Parties shall agree on any press release or other public announcement concerning this Agreement, other than an academic, scholarly, or scientific publication, prior to its public release, except to the extent any such release or announcement is required by law, rule, or regulation or the rules of any securities exchange. Notwithstanding the foregoing, each Party may, without prior approval from the other Party, make public announcement of the content of the abstracts submitted by Site in support of its Approved Project and the identity of research collaborators, including without limitation on Foundation’s website.

(c) Within thirty (30) days after creation of the final draft of any abstract, poster or paper analyzing or otherwise utilizing Data and prior to its submission for publication (each manuscript, a “Project Paper”), PI shall provide the IBD Plexus Publication Review Committee with a copy. PI shall use best efforts to seek publication of any Project Paper in accordance with generally accepted scientific standards.

(d) Project Papers will be reviewed by a subset of the Publication Review Committee on an ad hoc basis, provided that such review shall not exceed thirty (30) days from receipt of the Project Paper by such Committee. If there are no concerns with publication, then PI may move forward with publication efforts; however, if review of the manuscript indicates that issues need to be addressed, then the Project Paper will be reviewed by the entire Publication Review Committee, provided that such review shall not exceed sixty (60) days from receipt of the Project Paper by such Committee. Reasons for additional review include, but are not limited to, the following:

- Manuscript contains one or more egregious methodological errors
- Manuscript generates major reviewer concerns regarding methodology, findings and/or conclusions that are found to misinterpret the data and/or cohorts
- Manuscript is market research analysis
- Manuscript falls outside the scope of the approved Project

(e) In the event that the Committee provides comments to the PI, PI shall consider such comments.

(f) Foundation may make any Project Paper available through IBD Plexus after its publication, provided that it is permissible by the publishing journal and doing so does not compromise the publishability of any Project Paper.

(g) Any Project Paper shall include written acknowledgement of the Foundation: e.g., “The results published here are in whole or part based on data obtained from the IBD Plexus program of the Crohn’s & Colitis Foundation.”

The Foundation acknowledges that researchers with access to IBD Plexus resources may be required by third parties to provide copies of data they use in research projects for the purposes of validating or reproducing research results, for example, in order to publish their results in a journal, or because they are subject to other data

sharing requirements, for example, because they receive funding from the U.S. government.

This Policy sets forth the Foundation's commitment to support these researchers in fulfilling their commitments to third parties by allowing for the use of IBD Plexus data resources for validation, reproducibility, data sharing or other legitimate purposes.

The Foundation will use the following procedures to allow for access to IBD Plexus data as discussed in this Policy:

1) A researcher with access to IBD Plexus resources will notify the Foundation in writing promptly upon becoming aware that the researcher is subject to a requirement described in this Policy, including identification of the IBD Plexus data that is subject to this requirement, a description of the requirement, and the third party that imposes this requirement, as follows: [name and email address]. If the circumstances are such that the researcher cannot provide this notice, then the entity requiring access to the IBD Plexus data may provide this information to the Foundation.

2) The Foundation will cooperate in good faith to make available the IBD Plexus data that must be accessed for a purpose set forth in this Policy. Ordinarily, this will mean that a particular third party researcher or research team will be given access to IBD Plexus data through execution of a data use agreement with a researcher or research team for access to the IBD Plexus data only for the purpose of validating or reproducing the results as required by a journal policy, data sharing requirement, or other legitimate purpose. The Foundation may require other reasonable terms and conditions in return for providing access to IBD Plexus data, such as: that the third party researcher or research team not use the data for any purpose other than validation or reproduction of the research results, and that the data and all copies be securely stored so that the data is not used for any other purpose, and/or returned or destroyed.

3) In the event that a researcher with access to IBD Plexus data is subject to a requirement by a third party for which a data use agreement and provision of the data by the Foundation directly to a researcher or research team as set forth above is not sufficient, for example, if a U.S. government data sharing policy to which the researcher is subject requires deposit of a data set into a non IBD Plexus repository, then the Foundation will cooperate in good faith to allow that researcher to discharge his or her obligations with respect to that requirement.

4) Ordinarily, the Foundation will agree to allow a researcher who is subject to a requirement to deposit IBD Plexus data into a non IBD Plexus repository on the following conditions: (a) the researcher informs the Foundation in writing promptly upon learning that he or she is subject to such a requirement (and ideally at the time that the researcher submits a request to IBD Plexus for IBD Plexus data) and allows the Foundation the opportunity to ensure that such deposition requirement will include the license features set forth in Section 4(b) of this Policy and will not violate Section 5 of this Policy; and (b) the Foundation will approve deposition of IBD

Plexus data provided that the researcher deposits such data subject to a Creative Commons license with all of the Attribution (including identification of IBD Plexus as a source of the IBD Plexus data), Non Commercial and Share Alike features or their equivalent.

5) With respect to all of the foregoing in this Policy, the Foundation reserves its rights to, at its discretion, manage IBD Plexus so that the Foundation's obligations to third parties are not violated or otherwise compromised in its efforts to support researchers in fulfilling their responsibilities with respect to journal publication requirements, receipt of U.S. government funding and other requirements.

**8. No Representations or Warranties.** EACH PARTY MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO THE DATA OR OTHER SUPPLIED MATERIALS, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, OR THAT THE DATA OR OTHER SUPPLIED MATERIALS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK OR OTHER PROPRIETARY RIGHTS. ALL DATA AND OTHER SUPPLIED MATERIALS ARE PROVIDED ON AN "AS IS" BASIS.

**9. Risk of Liability/Indemnification.** Each Party shall assume all risk of and hereby does release the other Party, including without limitation, Foundation, IBD Plexus, its members, contributors, and their directors, officers, employees and agents (collectively, the "Releasees"), from all liability related to access to, storage and use of any data and other materials supplied to it by the other Party (the "Activities") and, only if Site is permitted by law to do so, each Party shall and hereby does indemnify, defend and hold Releasees harmless from and against all liability relating to the Activities, except to the extent that any such liability is caused by the gross negligence or willful misconduct of any of the Releasees.

**10. Remedies for Violation.** Any material violation of these terms and conditions shall constitute good cause for Foundation to immediately revoke permission granted for use of the Data and, upon such written notice from Foundation, Site and PI shall promptly cease all such use and at the election of Foundation return or destroy all such Data. Site agrees that any material violation of these terms and conditions may cause Foundation to pursue any and all available legal remedies.

## Appendix 3 – Material & Data Transfer Agreement

This Materials and Data Use Agreement (“Agreement”) is by and between the Crohn’s & Colitis Foundation (“Foundation”), a non-profit tax-exempt organization pursuant to Section 501(c)(3) of the Internal Revenue Code, with an address at 733 Third Avenue, Suite 510, New York, NY 10017 and XXX (“Site”), with offices at [XXX]. Foundation and Site each may be referred to herein as a “Party” or collectively as the “Parties” to this Agreement.

### Recitals

Foundation administers IBD Plexus, a resource for scientific researchers which includes patient biosamples, data and information, that was created to accelerate research, drive progress toward precision medicine, and transform the care of patients living with Inflammatory Bowel Diseases (“IBD”).

Site employs [XXX] (the “Principal Investigator” or “PI”), an IBD researcher approved by the IBD Plexus Project Selection Committee (“PSC”) to receive IBD Plexus biosamples and data (“Materials”) pursuant to an approved research proposal.

Foundation and Site agree that Site shall receive access to certain Materials on the terms and conditions of this Agreement.

### Agreements

For good and valuable consideration, the sufficiency of which is acknowledged, the Parties agree as follows:

**1. Materials.** Site shall receive the Materials identified at Exhibit A (“Provided Items”) for the purpose of conducting the project set forth in the PSC approved research proposal attached as Exhibit B (the “Approved Project”). Foundation agrees that the Provided Items shall not include any Protected Health Information, as that term is defined in the Health Insurance Portability and Accountability Act of 1996, as well as the implementing privacy and security regulations (collectively, “HIPAA”). Any data or information related to human tissue or sera samples shall be de-identified in accordance with the requirements set forth in 45 C.F.R. § 164.514(a) and (b) prior to disclosure to Site. Site shall maintain the Materials and other Provided Items in a secure environment and prevent their unauthorized use or disclosure and shall be solely responsible to remediate any breach or any unauthorized use or disclosure of Materials or Provided Items in its possession in accordance with all applicable laws and to the extent practicable. Site, upon knowledge, shall promptly report to Foundation any use or disclosure of Materials or Provided Items that are in material violation of any applicable law or this Agreement.

(a) Transfer/Disclosure of Materials. The Provided Items shall not be transferred to anyone not working on the Approved Project without the prior written permission of Foundation, provided that nothing herein shall prevent Site from meeting its obligations pursuant to any applicable law, or from meeting any obligation requiring the Materials to be made available in connection with publication of the results of the Approved Project.

Site may request additional use of the Provided Items but no such additional use shall occur without prior written permission of Foundation and, upon such written permission such additional use shall be an Approved Project.

(b) Subject PHI. Neither Site nor PI shall be permitted to use data to re-identify the individuals nor to contact them under any circumstances. In the event PI receives protected health information or information that is otherwise protected by any applicable law (any of the foregoing, “Subject PHI”), then PI shall not use such information to identify any individual nor contact them under any circumstances, shall only use such Subject PHI in accordance with applicable law, and PI shall return or destroy upon Foundation’s written request and option, or, if PI requests in writing and Foundation agrees that return or destruction is not feasible under the circumstances, then Site shall retain such information under these terms and conditions.

**2 Storage and Access to/Use of Materials.** Site shall safeguard storage of the Provided Items and prevent its use or disclosure in violation of this Agreement. Only the PI, and individuals appropriately trained in the handling of sensitive Materials under the PI’s supervision, will have access to and use the Provided Items.

**3 Compliance; Notice of Withdrawal.** PI shall use the Provided Items in compliance with all applicable laws. If Site receives written notice from Foundation that a patient, as identified using the unique coded identifier, whose Materials has been provided, wishes to withdraw permission for use of such Materials (a “Notice of Withdrawal”), then PI only shall use such Materials to the extent necessary to protect the integrity of the Approved Project.

**4 Notifications of Breaches and Security Incidents.** Site shall notify Foundation in writing as soon as possible, but in no event more than three (3) calendar days, after becoming aware of any breach or, or security incident involving Provided Items. Site shall be deemed to be aware of any breach or security incident as of the first day on which such breach or security incident is known to any of its officers or employees. Site shall identify as soon as practicable each individual whose Subject PHI has been, or is reasonably believed to have been accessed, acquired, or disclosed during such breach or security incident. Site shall cooperate in good faith, at its own cost and expense, in the investigation by Foundation of any breach or security incident.

(a) Prompt Corrective Actions. Site shall: (i) take prompt corrective action to remedy any breach or security incident, and (ii) mitigate, to the extent practicable, any harmful effect of a use or disclosure of Provided Items in violation of this Agreement.

(b) Notification of Corrective Action and Provision of Policies. Site will provide written notice as soon as possible but no later than ten (10) calendar days from the date that Site provided notice to Foundation, of: (i) the actions taken by Site to mitigate any harmful effect of such breach or security incident; and (ii) the corrective action Site has taken or shall take to prevent future similar breaches or security incidents.

## **5. Intellectual Property Rights (“IPRs”); New Materials/information; New Resources.**

(a) Claim of IPRs. Site and/or PI may claim IPRs on inventions or discoveries involving use of the Provided Items provided that Site and PI shall not claim any IPRs or any ownership rights, or permit any claim or assertion of IPRs or ownership rights, in any of or any part of, the Materials.

(b) Non Targeted Materials. If the Approved Project generates results not directed at a particular hypothesis, but rather is a preliminary exploration of the Materials (“Non Targeted Materials”), then, with respect to such Non-Targeted Materials, upon the earlier of: (a) one hundred eighty (180) days after the last grant of Materials to PI; (b) acceptance of an Approved Project manuscript for publication; or, (c) filing of a patent application, Site shall provide to Foundation in writing: (i) information about the status of the Approved Project, including identification of any New Resource (defined in Subsection (d)); and (ii) new raw Approved Project Materials in a manner that retains linkage of such materials to the Materials, which new raw Approved Project Materials may be released to third party researchers in connection with new research projects.

(c) Targeted Materials. If the Approved Project generates results directed at one or more particular hypotheses (“Targeted Materials”), then, with respect to such Targeted Materials, upon the earlier of: (a) five hundred forty (540) days after the last grant of Materials to PI; (b) acceptance of an Approved Project manuscript for publication; or, (c) filing of a patent application, Site shall provide to Foundation in writing: (i) information about the status of the Approved Project, including any New Resource; and, (ii) new raw Approved Project Materials in a manner that retains linkage of such Materials to the Materials, which new raw Approved Project Materials may be released in connection with new research projects.

(d) New Resources. If PI and/or Site creates any novel resources (which shall include new Materials, information and results) useful to scientific researchers that arise from use of the Materials, including without limitation that may be protectible as an IPR (“New Resources”), then Site shall notify Foundation and, if requested by Foundation, provide a copy of all such New Resources to Foundation at cost and without markup, for at cost distribution to scientists performing research into the causes of and cures for IBD, and provided that (i) any New Resource that is not new raw Approved Project Materials that may be



commercializable by Site only shall be made available by Foundation to non-commercial organizations, (ii) this sublicensable license shall be subject to Sections 5(b) and (c), (iii) such distribution will not grant to any third party any other right to such New Resources; and (iv) any recipient of such New Resources shall agree to substantially similar terms and conditions as the ones set forth in this Agreement, including without limitation release and indemnification of Site and PI as contributor for receipt, storage and use of any New Resource.

6. **Reporting Requirements.** Site is required to submit an annual progress report for the Approved Project, which will be reviewed by the members of the National Scientific Advisory Committee or Foundation staff.
7. **Notice.** Any notice required or permitted by this Agreement shall be made by one Party to the other Party as follows:

to Foundation:	to: Site
Justine Young	
Manager, Business & Research Ops	
Crohn's & Colitis Foundation	
733 Third Avenue, Suite 510	
New York, NY 10017	
E: <a href="mailto:jyoung@crohnscolitisfoundation.org">jyoung@crohnscolitisfoundation.org</a>	
T: (646) 965-2270	

8. **Press and Publication.**

(h) The Parties shall agree on any press release or other public announcement concerning this Agreement other than an academic, scholarly, or scientific publication, prior to its public release, except to the extent any such release or announcement is required by law, rule, or regulation or the rules of any securities exchange. Notwithstanding the foregoing, each Party may, without prior approval from the other Party, make public announcements regarding the content of the abstracts submitted by Site in support of its Approved Project and the identity of research collaborators, including without limitation on Foundation's website.

(i) Within thirty (30) days after creation of the final draft of any abstract, poster or paper analyzing or otherwise utilizing Data and prior to its submission for publication (each manuscript, a "Project Paper"), PI shall provide the IBD Plexus Publication Review Committee with a copy. PI shall use best efforts to seek publication of any Project Paper in accordance with generally accepted scientific standards.

(j) Project Papers will be reviewed by a subset of the Publication Review Committee on an ad hoc basis, provided that such review shall not exceed thirty (30) days from receipt of the Project Paper by such Committee. If there are no concerns with publication, then PI may move forward with publication efforts; however, if

EFFECTIVE DATE: JULY 2022

review of the manuscript indicates that issues need to be addressed, then the Project Paper will be reviewed by the entire Publication Review Committee, provided that such review shall not exceed sixty (60) days from receipt of the Project Paper by such Committee. Reasons for additional review include, but are not limited to, the following:

- Manuscript contains one or more egregious methodological errors
- Manuscript generates major reviewer concerns regarding methodology, findings and/or conclusions that are found to misinterpret the data and/or cohorts
- Manuscript is market research analysis
- Manuscript falls outside the scope of the approved Project

(k) In the event that the Committee provides comments to the PI, PI shall consider such comments.

(l) Foundation may make any Project Paper available through IBD Plexus after its publication, provided that it is permissible by the publishing journal and doing so does not compromise the publishability of any Project Paper.

(m) Any Project Paper shall include written acknowledgement of the Foundation: e.g., “The results published here are in whole or part based on data obtained from the IBD Plexus program of the Crohn’s & Colitis Foundation.”

(n) The Foundation acknowledges that researchers with access to IBD Plexus resources may be required by third parties to provide copies of data they use in research projects for the purposes of validating or reproducing research results, for example, in order to publish their results in a journal, or because they are subject to other data sharing requirements, for example, because they receive funding from the U.S. government.

This Policy sets forth the Foundation’s commitment to support these researchers in fulfilling their commitments to third parties by allowing for the use of IBD Plexus data resources for validation, reproducibility, data sharing or other legitimate purposes.

The Foundation will use the following procedures to allow for access to IBD Plexus data as discussed in this Policy:

1) A researcher with access to IBD Plexus resources will notify the Foundation in writing promptly upon becoming aware that the researcher is subject to a requirement described in this Policy, including identification of the IBD Plexus data that is subject to this requirement, a description of the requirement, and the third party that imposes this requirement, as follows: [name and email address]. If the circumstances are such that the researcher cannot provide this notice, then the entity

requiring access to the IBD Plexus data may provide this information to the Foundation.

2) The Foundation will cooperate in good faith to make available the IBD Plexus data that must be accessed for a purpose set forth in this Policy. Ordinarily, this will mean that a particular third party researcher or research team will be given access to IBD Plexus data through execution of a data use agreement with a researcher or research team for access to the IBD Plexus data only for the purpose of validating or reproducing the results as required by a journal policy, data sharing requirement, or other legitimate purpose. The Foundation may require other reasonable terms and conditions in return for providing access to IBD Plexus data, such as: that the third party researcher or research team not use the data for any purpose other than validation or reproduction of the research results, and that the data and all copies be securely stored so that the data is not used for any other purpose, and/or returned or destroyed.

3) In the event that a researcher with access to IBD Plexus data is subject to a requirement by a third party for which a data use agreement and provision of the data by the Foundation directly to a researcher or research team as set forth above is not sufficient, for example, if a U.S. government data sharing policy to which the researcher is subject requires deposit of a data set into a non IBD Plexus repository, then the Foundation will cooperate in good faith to allow that researcher to discharge his or her obligations with respect to that requirement.

4) Ordinarily, the Foundation will agree to allow a researcher who is subject to a requirement to deposit IBD Plexus data into a non IBD Plexus repository on the following conditions: (a) the researcher informs the Foundation in writing promptly upon learning that he or she is subject to such a requirement (and ideally at the time that the researcher submits a request to IBD Plexus for IBD Plexus data) and allows the Foundation the opportunity to ensure that such deposition requirement will include the license features set forth in Section 4(b) of this Policy and will not violate Section 5 of this Policy; and (b) the Foundation will approve deposition of IBD Plexus data provided that the researcher deposits such data subject to a Creative Commons license with all of the Attribution (including identification of IBD Plexus as a source of the IBD Plexus data), Non Commercial and Share Alike features or their equivalent.

5) With respect to all of the foregoing in this Policy, the Foundation reserves its rights to, at its discretion, manage IBD Plexus so that the Foundation's obligations to third parties are not violated or otherwise compromised in its efforts to support researchers in fulfilling their responsibilities with respect to journal publication requirements, receipt of U.S. government funding and other requirements.

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