

## Request For Applications

### Cohort for Pediatric Translational and Clinical Research in IBD

#### CAPTURE IBD

For further information, please contact:

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Summary	<p>The Crohn's &amp; Colitis Foundation is launching a research cohort called CAPTURE IBD, Cohort for Pediatric Translational and Clinical Research in IBD (CAPTURE IBD), which broadly aims to improve the treatment and understanding of pediatric IBD. High priority initial Specific Aims of the cohort and detailed study design will be informed by a steering committee comprised of site investigators and other relevant experts.</p> <p>CAPTURE IBD will follow pediatric IBD patients longitudinally through the course of their disease. Our target is to enroll 2,000 patients, over the course of 3 years, with linked clinical data, patient reported outcomes, biosamples and EMR data to advance the understanding of the course of IBD.</p> <p>Our goal is to select 10 sites in 2020 to start working on study design development with a study launch plan for 2021.</p> <p>CAPTURE IBD will be one of the cohorts under the IBD Plexus infrastructure which is designed to create a paradigm shift in disease research, and speed progress toward better diagnostics, treatments and – ultimately – cures for IBD.</p>
Important Dates	<p>Application Deadline: 09/25/2020</p> <p>Award Announcement: October 2020</p>

### **About the Crohn's & Colitis Foundation:**

*The mission of the Crohn's and Colitis Foundation is to cure Crohn's disease and Ulcerative Colitis, and to improve the quality of life of children and adults affected by these diseases.*

*The Foundation sponsors basic and clinical research of the highest quality through various funding mechanisms. Current funding opportunities offered by the Foundation can be found at*

*<https://www.crohnscolitisfoundation.org/research/grants-fellowships>*

#### **1. IBD Plexus Overview:**

IBD Plexus is a multidisciplinary shared resource designed to accelerate research, improve patient care, and facilitate novel research that could lead to new treatment options.

In order to meet research goals, IBD Plexus will build a resource comprised of the following components:

- a. Robust registry of longitudinal patient-reported and clinical data linked to derived multi-omic / expression biosample data.
- b. Biosamples (peripheral blood, intestinal tissue, and stool) stored and accessed through the IBD Plexus biobank with sophisticated laboratory information management system (LIMS).
- c. Large data management system with cleaned and aggregated patient-reported, clinical and biosample metadata.
- d. Portal for researchers to: 1) access aggregated de-identified data to aid in hypothesis generation, proof of concept studies, and study feasibility, 2) submit research proposals for data and/or biosamples, 3) disseminate raw data back into the solution, and 4) connect to high performance cloud computing environment.

#### **2. CAPTURE IBD: Cohort for Pediatric Translational Research in IBD:**

The Cohort for Pediatric Translational and Clinical Research in IBD (CAPTURE IBD) is a connected network of sites, which will follow pediatric IBD patients longitudinally throughout the course of their disease. The objectives of CAPTURE IBD are broadly to improve the treatment and understanding of pediatric IBD, with the ultimate goal of improving the quality of life of patients with IBD. Each site will collect longitudinal clinical data, patient-reported outcome (PRO) data, and serial biosamples through the course of the patient's disease. Specific aims and study design will be defined by the steering committee.

Highly engaged and enthusiastic sites are crucial to the success of CAPTURE IBD. Our goal is to select 10 sites, who will enroll 2,000 pediatric patients over the next 3 years. The Principal Investigators (PIs) of these 10 vanguard sites, in addition to other relevant experts, will form the steering committee, which will hone the objectives, protocol, data and biospecimen plans to meet the needs of the pediatric IBD

patient and research community. Linkage of clinical and patient-reported outcomes to biosample and derived multi-omic data will support translational research, and speed progress toward better diagnostics, treatments and ultimately, cures for IBD.

Data and samples will be then stored within the IBD Plexus infrastructure and can be used for clinical basic, and translational research. As a cohort enrolling pediatric patients at different stages of IBD, CAPTURE IBD will serve as a platform for clinical studies and translational research targeting children and adolescents with IBD. Additionally, this cohort can be used to identify the feasibility of early-stage clinical trials and/or observational studies, and in some cases to directly recruit patients to participate in such studies.

Other than requiring participants to be under 18 years old at time of enrollment, it is anticipated that the inclusion criteria for CAPTURE-IBD will be quite broad. Detailed inclusion/exclusion criteria will be determined by the steering committee, which will also develop the final protocol. The anticipated design of broadly enrolling all patients with IBD provides the greatest flexibility for future use of this cohort.

Pragmatism will be a priority in the design of CAPTURE IBD. We plan for enrollment and follow-up visits to occur in parallel with routine clinical or procedure visits so that data and sample collection are collected with minimal interruption of usual care and do not require additional visits from the patients.

### **3. Main Objectives**

The Cohort for Pediatric Translational and Clinical Research in IBD (CAPTURE IBD) broadly aims to improve the treatment and understanding of pediatric IBD. Specific aims of the cohort will be determined by the cohort steering committee.

### **4. Data and Biosample Collection**

Data and biosamples will be collected at the time of routine clinical encounter, allowing participants to continue in usual care without adding burden of additional study specific visits. The main advantages of this design are as follows: there is a limited barrier to participation; the results should be generalizable to usual care outside of the research centers; and implementation of quality of care initiatives would not be hampered by the study protocol.

In addition, medical data will be extracted from the clinician's electronic medical record (EMR) system using a secured electronic data extraction workflow.

Collection of blood, stool, and intestinal tissue involves additional steps beyond usual care. In addition to supporting the collection of clinical data, a research coordinator will be needed to obtain and process the samples. We expect biosamples will be collected at time of enrollment, around the time that the patient undergoes lower and/or upper endoscopy, as well as during their routine clinical visits when necessary.

The 10 selected sites will work together to determine the study design and collection strategies for:

- a. Baseline data collection
- b. Longitudinal data collection
  - Clinical disease activity
  - Disease phenotype information
  - Endoscopy disease activity
  - Laboratory evidence of disease activity
  - Patient Reported Outcomes
- c. Retrospective and Prospective EMR data collection
- d. Biosample collection
  - Peripheral blood
  - Intestinal tissue
  - Stool

## 5. Benefits of Participating

The Foundation seeks to select **10 sites** to join CAPTURE IBD for this round of funding. These 10 sites will guide the direction of the CAPTURE IBD cohort, advising on activities such as honing the specific aims, development of the study protocol, data/biosample collection and sharing strategies, study design, statistical methodology and publication policies.

Participation at this early phase is critical to the success of the program. Through participating, you will receive the following benefits:

- Foundation support:
  - Assumes all direct costs of the large data management system and biobank: IBD Plexus
  - Provides funding to support the PI and support data and biosample collection.
- Selected sites opportunities:
  - Drive the pediatric research agenda through prioritizing the research goals and design of hypothesis driven questions.
  - Can apply for a seat on the IBD Plexus Project Selection Committee and CAPTURE IBD sub-committees.
  - Can participate in cohort ancillary studies and collaborative projects.
- In addition, individual sites will have the ability to:
  - Access to clinical and biosample data (e.g., molecular data) from the other sites and other IBD plexus cohorts through submission and approval of a proposal to the IBD Plexus Project Selection Committee.
  - Receive extracted clinical data, patient-reported data and derived biosample molecular

data for your site's participants in an analytical format (no proposal submission needed).

- Access to research tools (at no cost) including an online data exploration tool which generates quick insights to aid in activities such as hypothesis generation.
- Form relationships with other stakeholders in the program such as the pharmaceutical industry, including the potential for your site to be recruited for additional funded studies through industry sponsors.
- Partake in annual investigator meetings.

## **6. Selection Criteria**

Application from sites interested to join the cohort will be evaluated based on the following criteria:

1. Demonstrate the ability to enroll unique patients (2-3 patients a week)
2. Ability to enroll patients with diverse disease severity
3. Ability to enroll patient population with diverse ethnic/race and socio-economical background
4. Ability to enroll newly diagnosed patients
5. Presence of an existing clinical research team (e.g., nurse or coordinator and/or data entry staff) to support clinical data and sample collection or clear plan that lays out strategy to bring onboard the appropriate research staff
6. Experience with and ability to collect, process, and ship relevant biosamples to IBD Plexus centralized biobank.
7. A Principal Investigator and co-Principal Investigator, who are highly motivated, that will organize, lead efforts at the site/practice and also meaningfully participate in steering committee meetings.
8. Demonstrated experience participating in both prospective studies and collaborative multi-center initiatives (basic, clinical or translational). If no prior experience, demonstrate a clear understanding of the keys elements to be part of a multi-center study.
9. Absence of potential conflicts of interest that cannot be managed in a way that would allow for participation as a CAPTURE IBD site
10. Clear plan to address potential competitive studies/registries that may affect enrollment or/and data/biosamples collection at the site
11. Ability to use a Central IRB
12. Bring unique experience, expertise and/or background to the cohort

## **7. Budget**

The Crohn's & Colitis Foundation is heavily invested in the success of this program. Budget will cover annual Lead PI salary at 0.10 FTE (NIH salary cap applies) and fringe benefit (may be split between a Lead and Co-PI), EMR data extraction support, start-up activities, and study activities

payments based on patient recruitment, biosamples and data collection per the payment table below.

Study Activity	Payment rate per patient/ visit
Patient consent form signed and baseline clinical data entered into clinical data collection tool	\$150.00
Blood collection/shipping at enrollment	\$50.00
Blood collection/shipping at time of procedures and clinical visit when applicable	\$50.00
Providing/shipping Stool kit to patient (at enrollment and at time of procedure)	\$25.00
Biopsies at time of procedure	\$150.00
Case report form data collection	\$35.00

Biosamples collection and shipping kits will be provided to sites.

Start-up activities as follow:

- \$4,000 for IRB preparation associated costs for Central IRB submission and other start-up expenses,
- \$10,000 for site coordinator
- \$20,000 advance against milestone payments on study activities.

Up to \$10,000 support funding toward EMR data extraction could be provided upon justification

Upon prior written authorization by Foundation, Site may include reasonable miscellaneous study supply costs (e.g., dry ice) on the study quarterly invoice, which shall be paid by the Foundation

10% indirect costs applied to the above

Patient incentives will discussed and determined by the steering committee.

The Foundation anticipates that it will continue to attract funding that will enable further growth and sustainability of the program beyond the next several years. Our goals are to make this a sustainable, long-standing resource to support cutting edge research in pediatric IBD.

## 8. Application Details

CAPTURE IBD Information session: Anyone interested in submitting an application and learning more about the project should plan to attend the **webinar on Wednesday, September 2<sup>nd</sup> 8-8:45pm (EST)**

Full Application Guidelines: Full applications should be submitted to the Senior Research Manager, Research Cohort Development and will be screened for responsiveness to this

announcement and fit to cohort objectives and needs.

Email to Cecile Norris at [cnorris@crohnscolitisfoundation.org](mailto:cnorris@crohnscolitisfoundation.org) no later than 11:59PM EST on **09/25/2020**.

**Your email should include all the items listed below:**

- a. A completed RFA questionnaire
- b. A cover page outlining the specific responsibility, role, and tasks to be performed by each team member
- c. Biosketch for the PI and co-PI using the new NIH format (5 pages). The first summary paragraph should not be generic, but should summarize your relevant qualifications to be an effective site investigator and what skills/expertise you would bring to the steering committee.
- d. A letter of support from leadership at your site/center (Division Director or Department Chair) for participation in this program

#### **8. Additional Information**

For additional details on the initiative, please reference the IBD Plexus and SPARC IBD webpages at:  
<http://www.crohnscolitisfoundation.org/science-and-professionals/research/IBDPlexus/>  
<http://www.crohnscolitisfoundation.org/science-and-professionals/research/IBDPlexus/cohorts-1-4.html>

If you have any questions and / or would like to request further information about this cohort, we encourage you to reach out to the Senior Research Manager.

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