Clinical Research Investigator-Initiated Awards in IBD

Request for Proposals (CRIA-SRA Awards & CRIA-CDA Awards)

Application Guidelines and Policies

Crohn's & Colitis Foundation
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New York, NY 10017
http://www.crohnscolitisfoundation.org

E-mail contact: cria@crohnscolitisfoundation.org

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

March 2026 revised

Key Dates

Application Stage	Fall Cycle Timeline	Spring Cycle Timeline
Pre-Application Available	April	Oct
Pre-Application Deadline	June	Dec
Full Proposal Deadline	July	Jan
Review Period	Sept-Oct	April-May
Award Notifications	Dec	June
Earliest Start Date	Jan	July

**NOTE: Dates and submission cycles are subject to change by the Foundation. Please refer to the Foundation website or contact Foundation staff.*

1. Overview and Scope

The mission of the Crohn's & Colitis Foundation (Foundation) is to find cures for Crohn's disease and ulcerative colitis, collectively known as inflammatory bowel disease (IBD), and to improve the quality of lives of patients living with these diseases, in other words, to care and cure. In approaching this challenging mission, we focus on several key principles that need to be considered in applying for a Clinical Research Investigator-Initiated Award in IBD (CRIA-SRA or CRIA-CDA):

- **Patient Centricity**: that is, keeping the patient and caregiver at the center of what we do. Patients and caregivers participate in the strategic planning and research review committees of the Foundation. ***To ensure that research proposals are patient centric, patients and/or caregivers must be included as part of the clinical research team. Involved patients/caregivers must submit a letter commenting on the feasibility of the clinical research and the reasons/barriers that will influence why patients will participate.***

- **Research Priorities**: *Challenges in IBD Research* outline the research priorities in IBD research that need to be overcome to accelerate the science towards our mission. For clinical research the priorities include:
    - Incidence and prevalence of IBD, particularly minority health
    - Medication positioning to increase therapeutic effectiveness
    - Utility of therapeutic drug monitoring (TDM)
    - Pain management
    - Healthcare economics and resources utilization, particularly in the context of multidisciplinary care

  While other research topics will be considered for funding, there needs to be a compelling clinical rationale to justify a focus outside of the priority areas.

- **Support for Junior Investigators**: The Foundation seeks to encourage a career of independent clinical investigation in the area of Crohn's disease and ulcerative colitis research. The CRIA supports junior investigators through one mechanism:
    - **Career Development Award (CRIA-CDA)**: Lead PI is a junior faculty member, and a career development plan must be included in proposal submission.

The objective of the CRIA is to directly impact patient care by addressing an important clinical question by studying people either through direct interaction with the people and/or indirectly by studying people through large databases, such as claims data or administrative data. (Details follow under *Definition and Guidance for Clinical Research Proposals*.) Therefore, the expectation is that the research findings from funded CRIAs will result in highly-cited publications, citations in clinical guidelines, and/or follow-on funding to advance the research further.

2. Applicant Eligibility

- **Senior Research Award (CRIA-SRA)**: The lead PI must be a faculty member (minimum Assistant Professor level) with a successful track record of funded clinical research projects (preferably NIH-funded) and relevant expertise in the clinical question to be addressed. **NOTE: For CRIA-SRA applicants only**, we are no longer requiring for the research team to include at least one junior Co-PI (Instructor or Assistant Professor, prior to receiving an independent RO1 grant or international equivalent) with experience in IBD research, who is committed to IBD research as a part of his or her career development.

- **Career Development Award (CRIA-CDA)**: The lead PI must be a junior faculty member (Instructor or Assistant Professor, prior to receiving an independent R01 grant or international equivalent) with experience in IBD research, who is committed to IBD research as a part of his or her career development. Generally, junior Co-PI candidates should not be more than ten years beyond the attainment of their doctoral degree at the time of application. The Foundation is sensitive to personal-related matters that impact career trajectories. Applicants who have taken leave from their career (e.g., parenting of a child, childbirth, long-term care of a parent/spouse/ child/dependent, personal health issues) or been impacted by the Covid-19 pandemic that puts them outside of the eligibility time frame for the award mechanism should feel free to reach out to Foundation staff ahead of their application submission. We aim to be flexible and adjust these time frames if necessary and appropriate. This can be captured in the applicant's coverletter.

- PI and Co-PI must be employed by institutions (public non-profit, private non-profit, or government) engaged in health care and/or health related research. International applicants are also eligible to apply, and there are no geographical restrictions regarding research site locations.

3. Proposal Eligibility

- Proposed study matches the scope of the program, as described in the RFP, and eligibility criteria are met.
- Only one proposal may be submitted per submission date.
- Applicants for a CRIA-CDA may not simultaneously apply for a CRIA-SRA. CRIA-CDA and CRIA-SRA applications will compete for the same funding.
- Applicants for a CRIA may not simultaneously submit another application on the same research topic for a Litwin IBD Pioneer award, Clinical Research Network Award or Research Initiative.
- Successful applicants may not hold concurrent Crohn's & Colitis Foundation CDAs or SRAs; however, applications for new projects may be submitted 6 months prior to the termination of the awardee's current grant.

4. Grant Funding Terms

- The total budget can be requested for up to three years. Specific milestones will be agreed upon as part of the funding process, and continued funding is dependent on achieving these milestones, which will be reviewed scientifically and administratively.
- Indirect expenses must not exceed 10%.
- Salary request for the senior researcher cannot exceed NIH salary caps, and for junior researchers, the total salary support cannot exceed $100,000/year; fringe cannot exceed 30% of salary. CRIA-CDA recipients are required to dedicate at least 35% of their time to the Foundation's funded project, while their institutional clinical effort cannot exceed 40% of their time. CRIA-SRA lead PIs are required to dedicate a minimum of 10% effort, while the junior Co-PIs who participate on a CRIA-SRA are required to dedicate at least 25% of their time to the Foundation's funded project, while their institutional clinical effort cannot exceed 50% of their time. An institutional representative will be required to confirm this information as part of the proposal submission process.
- The maximum budget request: $250,000/year in total costs (10% IDC maximum allowed), for three years. The Foundation will no longer accept requests from applicants to exceed this budgetary threshold.
- A budget justification for the amount requested is required. Details should allow reviewers to assess the feasibility of how the requested amounts for personnel and non-personnel expenses will be spent to carry out the proposed activities. If the research (e.g., clinical trial) is designed for more than the three-year period, a plan for securing funding for additional years must be included. If parts of the costs of the research are to be provided by other sources, these contributions should be presented in detail along with supporting letters from appropriate individuals and/or institutions. While the Foundation may look favorably upon funding from outside sources to enable completion of the research proposal, the Foundation reserves the right not to fund projects that are supported completely or in part by another source.

  If there is institutional support (PI faculty package, discretionary funds, etc.) for the proposal, a description of any institutional support provided by the institution should be uploaded to the section "Evidential Enclosure". The details should include institutional commitment to support the applicant's salary during the proposed funding period; and the current term of the applicant's appointment. Please note that the institutional support does not decrease the chances of obtaining support from the Foundation, rather, such support is frequently considered by the review committee as important evidence for institutional commitment to the investigator and the proposed research project.

- *Note: a travel budget should be included to attend the Crohn's & Colitis Congress, which is usually held annually in January. Additionally, in the second year of the award, there must be set aside a travel budget to attend the Foundation's Investigators Research Symposium, which is held near New York City.*

5. Definition and Guidance for Clinical Research Proposals

For the purposes of the CRIA RFP, clinical research is defined to directly impact patient care by addressing an important clinical question by studying people either through direct interaction with the people and/or indirectly by studying people through large databases, such as claims data or administrative data. Therefore, clinical research proposals could include clinical trials, registries or cohort studies with active patient enrollment, health services research, epidemiology, comparative effectiveness, or similar types of methodologies. While studies may include the collection and analysis of blood, tissues, or other samples, the primary purpose of the direct interaction with people must be to directly impact patient care. Studies with a primary aim to collect biosamples and/or develop predictive markers are considered by the Foundation to be translational research and outside the scope of the CRIA RFP award mechanism.

The submitted Research Plan should incorporate information regarding the following:

- The need for the study in the context of priorities outlined in the *Pragmatic Clinical Research* publication within the 2024 *Challenges in IBD Research*, and how the results would impact prevailing practice in this area. There needs to be a compelling clinical rationale to justify a focus outside of these priority areas.
- A detailed discussion of the experimental design, including a rationale for the selected design, primary and secondary endpoints, and source of patient enrollment and/or patient data to be used to accomplish the Specific Aims.
- A list of inclusion and exclusion criteria. The procedure(s) to be utilized for assignment of patients to experimental groups, if relevant, should be described. Potential biases in the proposed protocol and how they will be addressed should be presented. Clinical, laboratory, and physiological tests should be described including methods of randomization if used. Assumptions and calculations to arrive at the proposed sample size should be included.

  The availability of patients and/or patient data for the proposed study, including the specific characteristics that are required for the group should be presented. For clinical trials or studies relying on patient registries, approaches should be outlined for the recruitment, retention, and follow-up of the required number of patients. Projected rates of patient enrollment should be included in a targeted enrollment table. Data should be presented supporting recruitment and retention estimates. If enrollment falls behind projected levels, funding may be delayed or terminated. A timetable for completion of the various phases of project should be presented.

  Plans should be described for patient protection, including informed consent, monitoring of data for safety, and early termination as required. At the time of funding, appropriate informed consent forms, certification of approval from the Human Studies Committee (or its equivalent) for each participating institution, and GCP training certificates should be submitted to the Foundation.

  The organization of the study and how the trial will be managed should be described, including the function of any internal or external advisory committees and any data and safety monitoring groups. In multicenter trials, a description of the responsibility and role of a data coordinating center, and policies and methods concerning blinding of study results should be included. Accordingly, a plan should be submitted describing the procedure for the coordination of all

participating centers. A procedure or plan for data management should also be described, including data collection forms, if available. Data analysis methodology linking the analyses to the hypotheses to be tested should also be included. Primary and secondary end points should be clearly defined, justified, and related to the power calculations.

The Crohn's & Colitis Foundation does not assume responsibility for the conduct of the activities that the grant supports or the acts of the grant recipient as both are under the direction and control of the grantee institution and subject to the institution's medical and scientific policies. Grantee institutions must safeguard the rights and welfare of individuals who participate as subjects in research activities by reviewing proposed activities through an Institutional Review Board (IRB), as specified by the NIH Office for Human Research Protections, US Department of Health and Human Services. These policies apply to applicants and applicant institutions as well.

- Letters of commitment from each participating center, signed by the cooperating investigator and business official. Informed consent forms and evidence of Human Studies approval from all participating centers are required at the time of funding.

Applicants are advised to review the following publication and be prepared to address highlighted questions in their LOI: Zarin DA, Goodman SN, Kimmelman J. Harms from Uninformative Clinical Trials. JAMA 2019;322:813-814. 10.1001/jama.2019.9892

6. How to Apply

Pre-Application

The PI should submit the pre-application by the specified deadline (see Key Dates, above). The pre-applications will be evaluated based on the alignment of the proposed study with the scope of the program and the feasibility of success of the study, as described in more detail in Appendix A (below). Only investigators who submitted a pre-application and were invited to submit a full proposal are eligible to apply. The pre-application is reviewed seriously by the review committee that determines whether the applicant is invited to submit a full proposal. Each section of the pre-application should be completed fully to be eligible for funding consideration.

Important New Process: Resubmissions must now submit a new pre-application. This must be submitted on the pre-application deadline.

Resubmissions are allowed within three years of the initial CRIA application submission.

Full Applications

The investigators should provide a full research proposal and the accompanying document by the application deadline (see Key Dates, above) and according to the guidelines for proposal preparation and electronic submission, as described in more detail in Appendix B (below).

All applications should be submitted through the proposalCENTRAL portal at the following URL: https://proposalcentral.altum.com/.

Please refer to Appendices A and B for complete instructions of the application process. Appendix C includes the Foundation's IP policy.

7. Application Review

The application will undergo peer review by a clinical research review committee made up of members of the National Scientific Advisory Committee of the Foundation. The review committee will evaluate the proposal based on the following criteria:

- Alignment with the scope of this RFP and clinical potential of the study to impact the quality of life of people living with IBD. In other words, the study proposal "must address an important and unresolved medical question for the care of patients"[1] with IBD.
- Approach and project strategy: Sufficient preliminary data, goals, experimental plan and alternative strategies. In other words, "the study must be designed to provide meaningful evidence related to this question."[1]
- Feasibility of success: Demonstration of capabilities, personnel and infrastructure to conduct the proposed study, organizational resources, collaborators, and include a realistic plan for recruiting sufficient participants.
- Investigators' background and expertise: Demonstration of prior professional achievements in the field relevant to the proposed study, expertise in IBD research, publication track record
- Evaluation of the Career Development Plan for the junior PI or co-PI: Outline of training program (e.g., courses, workshops, etc.) and description of the career development research need, activities, milestones, and timeline
- Availability of appropriate facilities: Clinical, data management, and laboratory facilities should be described for all participating institutions, where applicable.
- Budget feasibility: The budget will be evaluated for feasibility for carrying out the proposal.

8. Progress Oversight and Reporting Requirements

- Funded investigators will be required to submit an annual progress report using the Foundation's progress report template found in proposalCENTRAL. Additionally, the PI will participate in monthly teleconferences to review progress on the project. These teleconferences will include Foundation staff, in addition to the PI and Co-PI (if relevant) of the project. Second and third year funding is contingent upon the favorable evaluation of the first- and second-year

[1] Zarin DA, Goodman SN, Kimmelman J. Harms from Uninformative Clinical Trials. JAMA 2019;322:813-814. 10.1001/jama.2019.9892

progress reports indicating that milestones have been met, or if not met, that appropriate mitigation plans have been developed, including realistic implementation plans and timelines. The final scientific report is due 90 days after the end of the project. Payments will not be processed while progress reports are delinquent. Payment can also be withheld if insufficient progress is made towards meeting milestones.

- Financial Reports: Annual financial reports are due 3 months after the end of the annual budget period. To allow for year-to-year comparison, the report should be submitted on the template provided in proposalCENTRAL and signed by a Financial Officer at the awardee institution. Failure in observing these requirements may delay payment. Final payments will not be made for awards with delinquent deliverables.
- Intellectual property: The Foundation requires notification of any intellectual property (IP) arising out of or resulting from this scientific proposal within 30 days of receiving an invention disclosure or other notice indicating existence of intellectual property. Grantee shall provide the Foundation with written notice, via proposalCENTRAL, of all inventions and patents as required by the Foundation Patent and Intellectual Property Policy (Appendix C). Upon accepting the award and signifying this Grant Agreement, both Principal Investigator and Authorized Institutional Officer express agreement and compliance with the terms of the Foundation Patent and Intellectual Property Policy.
- Publications and award acknowledgement: The Foundation shall receive timely and prior notice of any publications based upon the funded research and a copy of the publication should be uploaded onto the award record in proposalCENTRAL. The Foundation's support should also be acknowledged by the awardee and by the awardee institution in all public communication of work resulting from this grant, including scientific abstracts (where permitted), posters at scientific meetings, press releases or other media communications, and Internet-based communications.

9. Contact Information

For additional information regarding the application process please submit your queries to grant@crohnscolitisfoundation.org

10. Special Instructions for Foreign Applicants

Please be aware that you should give more details than you might be accustomed to, especially in the areas of background material and preliminary data, experimental design, and available facilities, budgetary items (particularly percent of effort and salary requests for key personnel). Please contact the Foundation at cria@crohnscolitisfoundation.org with any questions or seeking additional information.

All materials MUST be submitted in English.

Budget request must be in U.S. dollars. Awards will be made in U.S. dollars.

APPENDIX A: Pre-Application Submission Guidelines

Pre – Application

Each applicant must complete the pre-application form prior to submitting a full proposal for consideration. **The pre-application is reviewed seriously by the review committee and determined whether a full application is recommended to be submitted.** Each section of the Pre-Application should be completed fully to be eligible for funding consideration. Use the following outline to guide you through completing the Pre-Application. Please complete each section without naming the investigators, institutions involved, and references to publications. Failure to comply can result in an administrative withdrawal. A Biosketch or CV are not needed for the pre-application.

- This Pre-Application will undergo a blinded review process.
- It will be evaluated carefully to determine whether an invitation to submit a full application will be extended.
- Each section of the Pre-Application must be completed in full to be considered for funding.

Please use the outline below to guide your responses.

Components of the Pre – Application

Please complete the Pre – Application online in Proposal Central and adhere to all character limits and other requirements as outlined.

1. Pre – Application

a. Enter your project title.

i. Do not use abbreviations.
ii. Please limit the project title to 81 characters max.

b. Challenges in IBD Priority

iii. Please check one of the "Challenges in IBD" priority areas that will be addressed by your project.
iv. You may check "other," but please be prepared to explain why the topic of your research proposal should be considered a priority area for funding.
v. Link to the Challenge priority areas can be found here: https://academic.oup.com/ibdjournal/issue/30/Supplement_2?login=false

c. Type of Disease

vi. Indicate which subset of disease your project is focused on.

1. Crohn's disease

2. Ulcerative colitis

3. Inflammatory Bowel Disease (non-specified)

d. Type of Research

i. Indicate which type of research your project falls under: Basic or Translational.

e. Resubmission

i. Use the dropdown menu to indicate if this will be a resubmission of a previous full application that was not funded.

ii. Resubmission: This term applies to a previously approved Pre-Application or Letter of Intent that was followed by the submission of a full application but was not funded.

iii. Not a Resubmission: If a prior Pre-Application or Letter of Intent was never submitted as a full proposal, it should be submitted as a new Pre-Application, which will require a review and potentially a new invitation for a full proposal.

1. APPLICANT/PRINCIPAL INVESTIGATOR (PI) INFORMATION

a. PI is defined as the one person responsible to the Foundation for scientific and technical direction of the project.
   i. While a project can have Co-PIs and senior collaborators, only one person and awardee organization can be the point of contact responsible for technical and financial management of the award scientific outcomes and reports.

b. In this section, input basic information about yourself and your institution.

c. On this page, you are also able to link your ORCiD ID, if you have one.

2. APPLICANT/PI DEMOGRAPHICS

a. In this section, respond to standard demographic questions about yourself.

b. Please note that completing this survey in Proposal Central is voluntary. Responses are confidential, and demographic information will not be used in grant funding decisions.

c. The Crohn's & Colitis Foundation strives to create funding programs and services that represent the full diversity of the community. We regularly monitor the operation of the program's application, review, and award processes to identify and address barriers to advancing a community and culture that is inclusive and supportive of people from diverse backgrounds. We ask the demographic questions to ensure that we are meeting these goals.

d. *The submission of this information is optional*, and declining to provide information will not affect the consideration of an application for award funding from the Crohn's & Colitis Foundation. This information will assist us in better understanding the demographic profiles of applicants and advancing our efforts to ensure an inclusive and equitable process for our programs.

3. *SUMMARY PAGE*

Please note that this Pre-Application is blinded *(initiated in the Spring 2025 Review Cycle)**;** reviewers will not have access to your institution or names. The Summary Page will be the only information accessible to reviewers. Please complete each section without naming the investigators or institutions involved, and references to publications. Failure to comply can result in an administrative withdrawal. A Biosketch or CV are not needed for the pre-application.*

a. Background & Rationale: Provide the context for the project, the unmet need in knowledge, and application to clinical science. Include a rationale for the design of this proposal to address these questions. No references. Complete without naming the investigators or institutions involved.

b. Relevance to IBD: Describe how this proposal will advance understanding IBD pathogenesis or result in developing of new IBD treatments and diagnostics.

c. Specific Aims & Methods Proposed: List each aim of the proposal, a summary of the methods employed for each aim, and approaches to analysis of data.

d. Eligibility Quiz: Answer the questions in this section to determine your eligibility for the grant, which will enable you to continue with the Pre-Application review process. Note: Please read these questions carefully and respond truthfully and accurately.

4. INSTITUTION AND INSTITUTIONAL CONTACTS

a. Identify your institution and input basic contact information.

b. Add institutional contacts.

5. *ENABLE OTHER USERS TO ACCESS THIS PROPOSAL*

b. In this section, add anyone you want to be able to access and view your application.

6. VALIDATION PAGE

c. This page will check your completed form for any inaccuracies or missing fields.

7. SIGNATURE PAGE

d. In this section, you must digitally sign the form to indicate it is complete and accurate.

8. SUBMISSION PAGE

a. This page will officially submit your Intent to Apply form.

b. The Foundation highly recommends saving a copy of your completed form.

9. FUNDING OPPORTUNITIES

e. If you would like to be notified about current and upcoming funding opportunities offered through the Foundation, provide your email here.

APPENDIX B: Full Application Submission Guidelines

General information

Before submitting the full application, please read the Crohn's & Colitis Foundation's *Clinical Research Investigator-Initiated Award in IBD* RFP document to ensure that the proposed study matches the scope of the program and that eligibility criteria are met.

See Key Dates above and website for due dates of proposals.

The application should be submitted to proposalCENTRAL at: https://proposalcentral.altum.com

Paper copies of the application are not accepted.

To start the application process, follow the steps below:

1. If you are a first-time user, 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.
2. Once you are a registered user, please 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.
3. Locate the "Clinical Research Investigator-Initiated Award in IBD" announcement and click "Apply now".
4. To activate the navigation bar on the left, enter the title of your proposal on the title page and "save" the application. The navigation bar on the left will now become interactive for you to continue your application.
5. Once completed, please validate and submit the application.

Detailed Instructions for Electronic Submission

Formatting the Application

Applicants must adhere to the following instructions in completing the proposal sections that make up the electronic version of the application.

1. *Please remember to insert your name in the header on each form in the attachment section.*
2. *Font size: Use 11-point Times New Roman or 10-point Arial as the minimum font size for the text of the application. A 9-point Times New Roman or 8-point Arial font type may be used for figures, legends, and tables.*
3. *Single-spaced text is acceptable, and space between paragraphs is recommended.*
4. *Margins: The margins of your text should be at least 1" inch on all sides, unless a form with different margins is supplied in the Application Templates or Forms.*

Title page

Enter your title and “save” the application

Templates and Instructions

PI Biosketch and a New Vendor Form are available for download.

New Vendor Form *Required (part of Attachments section)

Complete this form to authorize your institution to receive payment from the Foundation. This document contains instruction on how payment will be transferred to your institution and should not include information on the Investigator. This is required even if institution has received Foundation funding in the past.

Enable other Users to Access the Proposal

Add personnel that can have access to review and edit the proposal.

Applicant /PI

Principal Investigator (PI) is defined as the one person responsible to report to the Foundation for scientific and technical direction of the project. Although there may be a Co-PI, only one person can be indicated as the main point of contact. Note: If the research (entirely or partially) is to be conducted in the Co-PI’s laboratory, a subcontract budget needs to be proposed.

Institution and Contacts

Provide contact information of the signing staff officials at the institution where the lead PI is located and where the study will take place.

Junior Co-PI, Co-PI(s), Collaborator, Key Personnel, and Patients/Caregivers

Add the roles and the contact information for Co-Principal Investigator (Co-PI), key personnel, and patients/caregivers whom you include on this application.

Effort

Percentage Estimation of Amount of Time Allocated to this Project: Describe how the time (in percentages of full-time effort) is allocated in your current position at this institution. CRIA-CDA recipients are required to dedicate at least 35% of their time to the Foundation's funded project, while their institutional clinical effort cannot exceed 40% of their time. CRIA-SRA lead PIs are required to dedicate a minimum of 10% effort.

Mentor Information for CRIA-CDA Applications

Provide information regarding the researcher who will be mentoring you on this study. All applications must have at least one mentor at the sponsoring institution who agrees to be available to provide advice and guidance to the awardee during the entire CRIA-CDA.

Career Development Plan

The PI is asked to submit a ≤ 3-page career development plan for the Junior Co-PI or for oneself if the lead PI is a junior researcher, which should include a description of the career development research need, activities, milestones, and timeline. For the CRIA-CDA, the career development plan should align with the plan described in the required mentor's letter of support.

Challenges in IBD Research Priority

Please check one priority area that is addressed by your project, or if not related to *Challenges in IBD*, why the research proposal is so compelling that it should be considered a priority for funding.

Lay Summary

The Foundation has instituted a Stakeholder Reviewer Program, in which selected lay patients or caregivers participate as voting members of review committees. The lay summary should be a clear, concise overview in simplified language, appropriate for non-scientific reviewers to enable them to score the proposal appropriately. Please provide enough essential information that the Stakeholder Reviewers will be able to evaluate your application. The lay summary should answer the following questions:

1. Is this project proposing to answer an important and unresolved medical question that can directly impact patient care in IBD? How will the results of this study (whether positive or negative) impact clinical practice and patient care in IBD?
2. How is this question important to the research priorities outlined in the **Pragmatic Clinical Research** publication of *Challenges in IBD Research*? If not focused on *Challenges*, what is the compelling clinical rationale to justify a focus outside of the priority areas?
3. How do the hypothesis and specific aims support answering this question? Will the evidence generated from this study be sufficiently meaningful to answer the proposed clinical question?

4. Is the study design feasible (i.e., will patients enroll in this study or will the investigators be able to access the data they need?) Will the research team be able to successfully conduct this study and appropriately analyze the results in a valid manner?

Scientific Summary of the Project

Summary should provide a clear, concise overview of the proposed work, including background, objective, or hypothesis and supporting rationale, and specific aims of the study for general scientific audience. Please highlight how your project is addressing one of the priority research areas described in the *Challenges in IBD Research*, or if not related to *Challenges in IBD Research*, why the research proposal is so compelling that it should be considered a priority for funding.

Reply to Previous Review (Required for resubmission applications only) (1 Page)

- For Resubmissions, upload a letter (1 page) that clearly and succinctly addresses the points raised in the previous review and directs the reviewer to the specific sections of the Research Protocol where revisions have been made. Revised portions of the text changed in response to the reviewers' comments should be highlighted.
- In this section, include copies of the following
    - Budget pages of previous application
    - Overall objectives and specific aims of previous application

Budget Period Detail

<u>Start and End Dates</u>

Specify date on which you expect to start this project. Enter dates for 3 years in 1-year increments.

Complete the e-form total budget.

Budget Summary Detail

The maximum budget request: $250,000/year in total costs (10% IDC maximum allowed), for three years. Salary request for the senior researcher cannot exceed NIH salary caps, and for junior researchers cannot exceed $100,000/year; fringe cannot exceed 30% of salary.

Justification of the budget for the 3-year period must be provided.

Current and Pending Financial Support

Please provide information on additional ongoing funding that currently supports this research project.

Organization Assurance

Human Studies Approval

All activities involving human subjects must be approved by an appropriate institutional review board (IRB) or equivalent prior to the start date of award. Indicate with "Yes" or "No" response, and if yes indicate date of approval and attach approval in that Attachments Section.

Copies of the IRB approval should be provided to the Foundation's Research Department. If approval is not available at the time of application, provide a date of anticipated approval. This approval must be received before the start date of the approved grant. **At the time of acceptance of funding, appropriate informed consent forms, certification of approval from the Human Studies Committee (or its equivalent) for each participating institution, and GCP training certificates should be submitted to the Foundation.**

Upload Attachments

Cover Page

Describe background and expertise of the PI, Junior Investigator, other Co-PI, relevant investigators, patients/caregivers, and the role/ tasks to be performed by each investigator

Research Plan/Protocol

The description of the proposed research project must include the following items in sufficient detail to permit evaluation of the scientific merit of the study. *This cannot exceed 9 pages, single spaced. The page limits distribution indicated below are included as a guideline and not required.*

- Overall Objectives and specific aims (no more than 1 page)
    - Briefly outline the general scientific objectives and state explicitly the important and unresolved medical question you are addressing that will directly impact patient care.
    - Describe concisely and realistically what the specific research described in this application is intended to accomplish and whether it will provide meaningful evidence to answer the medical question. Specifically outline Aims for year 1, year 2 or year 3, goals, 6-month-interval milestones and timelines. State any hypotheses to be tested.
- Background -including preliminary data (no more than 2 pages)
    - Outline the previous work in the area by others, and the preliminary data or previous studies by the investigator(s). Enough preliminary data should be included in the application to demonstrate that the project is feasible and that the investigator is likely to complete the project successfully in the duration of the grant.
- Detailed description of methods and protocols to be used (no more than 5 pages)

- Provide a detailed discussion of the experimental design, including a rationale for the selected design, primary and secondary endpoints, and source of patient enrollment and/or patient data to be used to accomplish the Specific Aims.
- Describe protocol to be used, method to assign patients to experimental groups, if relevant, procedures to assure compliance with/implementation of proposed protocol.
- Describe study patient population, including key inclusion/exclusion criteria, and assumptions and power calculations to arrive at the proposed sample size, which should relate to the primary and secondary end points.
- Discuss the kinds of data expected to be obtained and the means by which data will be analyzed and interpreted. A procedure or plan for data management should also be described, including data collection forms, if available. Data analysis methodology linking the analyses to the hypotheses to be tested should also be included.
- If relevant, outline approaches for recruitment, retention, and follow-up of required number of patients. Projected rates of patient enrollment should be included in a targeted enrollment table. Data should be presented supporting recruitment and retention estimates.
- Discuss potential difficulties and/or limitations of the enrollment plan and alternative approaches to achieve aims.
- Describe the organization of the study and how it will be managed, including the function of any internal or external advisory committees and any data and safety monitoring groups. In multicenter trials, you should provide a description of the responsibility and role of a data coordinating center, and policies and methods concerning blinding of study results. Accordingly, a plan should be submitted describing the procedure for the coordination of all participating centers.
- Describe plans for patient protection, including informed consent, monitoring of data for safety, and early termination as required.

- Significance and relevance of the proposed research to Crohn's disease and/or ulcerative colitis and to *Challenges in IBD Research* priorities (no more than 1 page). Is this study answering an important and unresolved medical question that will directly impact patient care?
- Justify the significance of the results of this project on the quality of life of people living with IBD. How will the results of this study (whether positive or negative) impact clinical practice and patient care?
- Project feasibility to carry out the proposed studies (one or two paragraphs)
  - Describe factors, such as collaborating sites willing to participate in this project, patient enrollment strategies/mitigation plans, which will increase the feasibility of this project.
- References (no more than 2 pages, not counted as part of the 9-page limit)
  - Literature citations should be listed in this section, at the end of the Research Plan.

Timeline and Milestones (Required, 1 page)

Timeline for completion of project (Gantt chart or similar format): List of milestones projected for every six months of the project period.

Letter from Patient/Caregiver regarding Research Feasibility

- ***Patients/caregivers who are part of the research team must submit a letter commenting on the feasibility of the clinical research and the reasons/barriers that will influence why patients will participate.***

Biosketches for Key Personnel

Biosketch (NIH format) for PI, Co-PI, patients/caregivers (required), and additional key personnel (optional). A brief resume-style biography can be substituted for NIH format biosketch for the patients and caregivers.

Biosketches for Mentor(s) (only for CRIA-CDA applicants)

Attach the NIH Biosketch for all Mentor(s).

Letter of Support from Mentor (only for CRIA-CDA applicants)

The letter from your mentor(s) should include the following information:

- Description of the facilities and resources available for the proposed project
- Outline of training program (i.e., courses, workshops, etc.) and career development plan for the applicant

Career Development Plan

Upload the career development plan (≤ 3-page) for the Junior Co-PI (CRIA-SRA) or the lead PI for a SCRIA-CDA, which should include a description of the career development research need, activities, milestones, and timeline. For the CRIA-CDA, the career development plan should align with the plan described in the required mentor's letter of support.

Additional Mentor Page- Optional (only for CRIA-CDA applicants)

Upload information on additional mentor(s), who are not already listed on the main application

Applicant Research Experience Required (only for CRIA-CDA applicants)

Research Experience (template available in Downloads section)

Letters of Collaboration

Attach supporting letter(s) from collaborators, including letters of commitment from each participating center, signed by the cooperating investigator and business official.

Institutional Letter of Support

A letter from the applicant's Department Chairperson, or authorized institutional representative, guaranteeing protected research time commensurate with the percentage of effort/salary to be devoted to the research project.

References/ Appendices (Optional)

Uploaded reference material may include, but not limited to:

1. Other Letters of Support
2. Article references
3. Abstracts

Human Approvals- Optional

Upload IRB approvals for human research.

Signed Signature Pages

This document is generated by the PDFs and Signature Pages module after submitting all the forms and uploading all the required documents. Module PDFs and Signature Pages are located on the navigation bar on the left-hand side.

Validate

Click *Validate* to check for any missing REQUIRED information or files. All missing required information will be listed on the screen.

PDFs and Signature Pages

Click *Print Signature Pages* to be signed by the applicant and the organization officials. Upload the signed document on the Upload Attachments module.

Click *Print Signature Pages and Attached PFD Files* if you would like to save the full application for your records. Do not upload the full application with the signed signature pages in Upload Attachment module.

Submit

Only the primary PI is authorized to submit the application.

APPENDIX C: IP Policy

All inventions or intellectual property ("Property") that results from research supported, in whole or in part, by grant awards from the Foundation must be reported in writing at the earliest possible time to Foundation. The grantee institution agrees to notify the Foundation within a reasonable time, preferably within 30 days, of receiving an invention disclosure or other notice indicating existence of a Property and to notify the Foundation immediately of the decision to apply for letters of patent or other legal protection for the Property. The Foundation agrees to keep all information confidential and not to release any information relating to such inventions, intellectual property or applications for protection to any third party, except as specifically set forth below or upon written agreement with the grantee institution, which consent cannot be unreasonably withheld. All patenting expenses or intellectual property application expenses shall be borne by the grantee institution.

Title to all Property shall reside with the grantee institution to the extent that such title is claimed by the institution under its institutional patent policy or procedure. If a grantee institution has no established institutional patent policy or procedure for administering inventions or intellectual property, or if the institutional patent policy or procedure does not claim rights for the institution or individual inventor, then Foundation shall have the right to determine the disposition of the Property rights in accordance with the provisions set forth below.

Distribution of income derived from any Property, which might include equity disposition, shall be shared by the grantee institution and the Foundation on mutually agreeable terms, such terms to be determined as soon as practicable, preferably prior to any licensing or commercial exploitation of the Property, and in any event no later than six months after first receipt of income. Such distribution shall be guided by the principle that the Foundation's proportion of the income shall be reasonably related to the Foundation's proportion of support for the research leading to the Property. The grantee institution agrees to notify the Foundation within a reasonable time of beginning negotiations with potential licensees and to notify the Foundation upon execution of any license or other agreement to commercialize the Property. The grantee institution will provide a copy of the license or other agreement, or an excerpt of the financial terms relevant to the Foundation's right to income from the Property together with the name of the licensee, the subject matter of the license and any other terms relevant to the foundation, including without limitation whether such license is exclusive or nonexclusive.

If any Property is made with or results from the joint support of the foundation and another organization, that organization, the grantee institution, and the Foundation will confer, in good faith, to arrive at a mutually satisfactory disposition of the Property rights guided by the principle that distributions of income be made in proportion to each party's contribution of support for the research leading to the Property.

No patent, patent application or other type of protection for a Property shall be abandoned without first notifying the Foundation and giving the Foundation a reasonable opportunity to take title to the Property.

If grantee institution does not effectuate a license to Property within four (4) years from the date that such Property is disclosed in writing through an invention disclosure or similar form to the grantee institution by the principal investigator, then the Foundation shall have the right to introduce to the

grantee institution one or more bona fide potential licensees and the grantee institution shall enter into good faith negotiations for license of the Property with such potential licensee(s). Upon consummation of any such license, the Foundation's introduction of the licensee to the grantee institution shall be counted to the benefit of the Foundation in calculating its share of any income from the Property.

The grantee institution agrees that when it licenses a Property, it will use reasonable efforts to obligate the licensee to exert its best efforts to commercialize or cause to be commercialized the Property as rapidly as practical, consistent with sound and reasonable business practices and judgment, and reserve the right to terminate the license upon a failure by licensee to do so. If the grantee institution relicenses any Property, the Foundation shall be entitled to a share of any relicensed Property income according to the principles set forth above.

The Foundation reserves the right to public acknowledgment for Property resulting from research supported by the Foundation. However, the Foundation's name and logo may not be used in association with any Property without the prior written approval of the Foundation.

The Foundation shall have use of the Property without payment of royalties or license fees solely for the use by the Foundation for its own intramural or public education purposes, but not for any of its grantee institutions.

Awardees and grantee institutions are responsible for ensuring that there are no inconsistencies in their consulting or business agreements that conflict with this policy