



Senior Research Award

APPLICATION GUIDELINES, PROCESS and FORMAT

Effective for Letters of Intent and Proposals due on or after **May 5th, 2020**

	Spring/Summer	Fall/Winter
Letter of Intent	November 8 th , 5:00 pm EST	May 5 th , 5:00 pm EST
Full Proposal	January 28 th , 5:00 pm EST	July 20 th , 5:00 pm EST
Review Period	April – May	October – November
Project Start Date	July	January

*Should the deadline date fall on a weekend or national holiday, the deadline will default to the following business day.

Please check proposalCENTRAL regularly for updates and date changes.

Crohn's & Colitis Foundation

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

<http://www.crohnscolitisfoundation.org>

General Submission Inquiries: grant@crohnscolitisfoundation.org

INTRODUCTION

The Crohn's & Colitis Foundation (Foundation) was established in 1967 to find the cause of and cure for Crohn's disease and ulcerative colitis, collectively known as inflammatory bowel disease (IBD). Support for our research program is provided by members and concerned individuals, corporations and philanthropic foundations.

The guiding mission of the Foundation is to stimulate and encourage innovative research in the basic, translational and clinical biosciences, which is likely to increase our understanding of the etiology, pathogenesis, therapy, and prevention of IBD. A focus on human mechanisms in IBD is particularly important for preclinical research.

Each year, the Foundation receives approximately 300 requests for Senior Research, Training, and Student support. All proposals are subjected to peer review to identify the most meritorious and innovative projects for funding.

The goal of the Senior Research Award (SRA) is to provide established researchers with funds to generate findings that have an impact on the field of IBD to advance the mission of the Foundation. This impact could be evaluated by various measures, including follow-on funding from other sources, such as the National Institutes of Health (NIH), publications with high impact, and related patents or citations within patents.

APPLICANT ELIGIBILITY

At the time of application, the applicant must:

1. hold an MD, PhD, or equivalent terminal degree and must be employed by an institution (public non-profit, private non-profit, or government) engaged in health care and/or health related research
2. have attained independence in his/her research efforts
3. be corresponding author for publications in the investigator's main area of research interest

Eligibility is not restricted by citizenship or geography.

PROPOSAL ELIGIBILITY

1. The submitted research proposal must address IBD.
2. Only one proposal may be submitted for this award per submission date.
3. Applicants for an SRA may not simultaneously apply for a Training Award (Career Development or Research Fellowship Award).
4. Applicants for an SRA may not simultaneously submit another application focused on the same research topic for a Litwin IBD Pioneer award, or Research Initiative.
5. Successful applicants may not hold concurrent Foundation SRAs; however, applications for new projects may be submitted 6 months prior to the termination of awardees current grant.

APPLICATION PROCESS

LETTER OF INTENT

Each applicant must submit a letter of intent (LOI) prior to submitting a full proposal for consideration. The LOI is reviewed seriously by the review committee and determines whether or not a full application is recommended to be submitted. Each section of the LOI must be completed fully to be eligible for funding consideration.

Resubmissions do not require an LOI. PIs intending to resubmit an application need to inform the Foundation by the LOI submission deadline by sending an email to loibypass@crohnscolitisfoundation.org with the following information:

- Subject line: Resubmission – LOI Bypass Request
- Body of email: PI name, project title, and original proposal number

Resubmissions are allowed within three years of the initial application submission. After three years, a new LOI is required.

The Grants team will have two bypass deadlines: 1st cycle June 1st-15th, 2nd cycle June 22nd - July 6th.

Resubmissions will be considered against the current Foundation Challenge Categories.

Components of Letter of Intent (LOI)

Please complete the LOI online in proposalCENTRAL, and adhere to the character limitations of each section and the other requirements as outlined.

Type of Research

Select one of the following

- Basic
- Translational

Challenges Priority

Please check one or more of the Challenges priority areas that is addressed by your project. 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. Link to the Challenge priority areas are [here](#).

Type of Disease

Select one of the following:

- Crohn’s disease
- Ulcerative colitis
- Inflammatory Bowel Disease non-specified

Eligibility Determination

Answers to the questions determine your eligibility for an SRA to enable you to continue with the application process.

Principal Investigator (PI)

PI is defined as the one person responsible to the Foundation for scientific and technical direction of the project. 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.

Organization Information

This indicates where the PI is located and where the study will take place. The Foundation does not make awards to individuals.

Key Personnel

Fill in key personnel, titles and affiliations

Project Title

Fill in the project title. Do not use abbreviations. Please limit the project title to 81 characters max.

Scientific Summary of Project

The Scientific Summary should provide a clear overview of the proposed work, including background (or hypothesis and its supporting rationale) and specific aims of the study. It should be concise but allow the review committee to assess the scientific merit and recommend it for full submission.

Relevance and Significance of the Project to IBD

Provide a description of how this project addresses unmet needs in IBD, is related to the Foundation's research priorities, outlined in Challenges in IBD, and how it will further both research and the Foundation's mission. The LOI must state how the research proposal is related to an area outlined in Challenges in IBD, or if not related to areas outlined in Challenges in IBD, the LOI must state why the research proposal is so compelling that it should be considered a priority for funding. If it is a proposal for preclinical research, then the project must demonstrate its relevance to human IBD mechanisms. Scoring will be negatively impacted if the LOI does not address these areas.

Link to the Challenges in IBD: https://academic.oup.com/ibdjournal/issue/25/Supplement_2

Attachments

Please upload the following to this section:

- NIH Biosketch/CV for applicant (NIH biosketch format preferred).
- Up to three relevant publications (optional)

FULL APPLICATION

After review of LOIs, selected applicants will be informed whether their proposals have been selected for full application submission. There is an approximate three-week turnaround on LOI decisions after the LOI deadline has occurred.

Components of Full Application TITLE PAGE

Project Title

Fill in project title. If this is a resubmission, the title should be the same as the original application.

Type of Research

Select one of the following

- Basic
- Translational

Challenges 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. If it is a proposal for preclinical research, then the project must demonstrate its relevance to human IBD mechanisms.

Type of Disease

Select one of the following:

- Crohn's disease
- Ulcerative colitis
- Inflammatory Bowel Disease non-specified

APPLICANT/ PI

Principal Investigator

PI is defined as the one person responsible to the Foundation for scientific and technical direction of the project. Although co-PIs are permitted, only one can be indicated as the main point of contact.

Organization Information

This is where the lead PI is located and where the study will take place.

INSTITUTION AND CONTACTS

At the time of proposal submission, appropriate administrative officials will be required to sign off and submit the application. Please provide the name and address of the person, at the grantee institution, who will administer the grant. Please ensure that appropriate parties responsible to upload financial reports, fully executed award letters, organization assurances, and other institutional documents is given "Editor" or "Administrator" role for the proposal. Failure in observing that aspect may result in administrative delays.

KEY PERSONNEL

Please note any key members of this project such as collaborators, etc.

LAY SUMMARY

This summary for general audience should be a clear, concise overview in simplified language, appropriate for non-scientific reviewers. The lay summary should include the following information:

- What question will this project attempt to answer?
- Why is this question important to IBD? How would the results significantly advance the field of IBD research or impact patient care or quality of life?
- How does the research address the Challenges in IBD? or if not related to Challenges in IBD, why the research proposal is so compelling that it should be considered a priority for funding?
- What is the study design? How is it innovative?
- How do the hypothesis and specific aims fit with the Foundation's scientific priorities?

- If the research is successful, what next steps are needed to advance to the Foundation's mission to find cures for IBD and/or to improve quality of life for IBD patients?

In addition, include a brief glossary of any scientific terms included in your lay summary.

SCIENTIFIC SUMMARY

The Scientific Summary should provide a clear overview of the proposed work, including background, hypothesis and its supporting rationale, and specific aims of the study. It should be concise but allow the review committee to effectively assess the scientific merit.

Relevance of the Project to IBD

Provide a description of how this project is explicitly related to IBD and how it will further research to achieve the Foundation's mission. If it is preclinical research, then the project must demonstrate its relevance to human IBD mechanisms or explain why this should not be a priority for this particular research.

The above three sections will be evaluated as part of the application as well as used to inform the Foundation's National Board of Trustees and the general public about the funded project, therefore proprietary or confidential information should not be included.

BUDGET

Project Start Date

Date on which you expect to start this project. Funded applications for the Spring cycle would begin on July 1st. Funded applications in the Fall cycle would begin on January 1st of the following year.

Estimated Length of Project

SRA projects can range from 12 to 36 months duration.

Percentage Effort

Inform the effort (in percentages) you estimate that will be needed to complete the proposed project. A minimum of 2 to 5% effort is required for the PI of an SRA. Describe how your time (in percentages) is allocated in your current position at this institution. An institutional representative will be required to confirm this information as part of the proposal submission process.

Percentage of Fringe Benefits Paid by Your Institution

Inform the applicable percentage of fringe benefits.

Detailed Budget

The total budget can be requested for up to three years. The request per year, including direct and indirect costs, may not exceed \$115,830. The Foundation indirect cost rate for the SRA is 10%. (So maximum request per year allowed is \$105,300 in direct costs + \$10,530 in indirect costs.)

The requested budget should reflect the personnel and other expenses to carry out the proposed activities.

SRAs are not meant to be a major source of a PI's salary. The award can support a portion of the PI's salary commensurate with the time allotted to the project. The salary request for the PI and all other personnel should be calculated as a percentage of the NIH salary cap, which is limited to the current Executive

Level II of the Federal Executive pay scale.

Requests for major equipment purchases (over \$5,000) are generally not considered. Any equipment purchased under a Foundation award is for the use of the PI, his/her collaborators and/or other researchers or trainees involved in this research project. Title to equipment shall be vested in the institution with which the PI is associated. In the event of an award transfer to another institution, equipment necessary for continuation of the research project purchased with the grant funds should be transferred to the new institution. Title to such equipment shall be vested in the

new institution.

Indirect costs over subcontracts:

- The prime recipient institution may request up to a maximum of 10% of the first \$25,000 of each subcontract.
- Subcontracting institutions may request up to 10% of indirect costs.
- The awardee institution is responsible for all oversight of the subcontract and must include financial accountings for the subcontract(s) in the financial reports

Budget Justification

It is the applicant's responsibility to justify the budget. Items not adequately justified will not be supported. Please provide a budget justification for the amount requested. Details should be provided to allow reviewers to assess how the requested amounts for personnel and non-personnel expenses will be spent to carry out the proposed activities.

CURRENT AND PENDING SUPPORT

Provide information on currently active projects and proposals pending review.

For pending applications, attach an abstract for each application you list in this section as an appendix in the Attachments Section.

Important Note on Scientific and Funding Overlap

The Crohn's & Colitis Foundation reserves the right not to fund projects that are supported all or in part by another agency. Projects are considered to overlap if there are any shared Specific Aims or budgetary overlap or overlap of percent of effort dedicated to the other project. The review committee will make the final decision regarding any questions of overlap.

There is an exception for institutional support (PI faculty package, discretionary funds, etc.). If this is applicable to this 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 the support of the applicant's salary; 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 proposed research project.

ORGANIZATION ASSURANCES

Human/Animal Studies Approval

All activities involving human subjects or vertebrate animals must be approved by an appropriate institutional review board (IRB) or equivalent within two months of the award date and is required for study activation and initial payment. Nevertheless, please indicate with "Yes" or "No" response, and if yes indicate date of approval and upload approved protocol in the Attachments Section.

ATTACHMENTS

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 section is **limited to 7 pages**, single spaced (1/2 inch margins). The lengths indicated below are included as a guideline and not required. HOWEVER, applications exceeding the page limit will not be reviewed.

Overall Objectives (one or two paragraphs)

- General scientific objectives

Specific Aims (1 page)

- Describe concisely and realistically what the specific research described in this application is intended to accomplish. Specifically outline Aims for year 1, year 2 or year 3, goals, deliverables and timelines. State any hypotheses to be tested.

Background - including preliminary data (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.

Methods and Materials to be used (3 pages)

- Provide a detailed discussion of the experimental design, procedures, and materials to be used to accomplish the Specific Aims.
- Describe protocols, including methods for new techniques, and explain the advantages over existing methodologies.
- Discuss the kinds of data expected to be obtained and the means by which data will be analyzed and interpreted.
- Justify the use of any animal models (i.e., choice of species, number used, etc.).
- Discuss potential difficulties and/or limitations of the proposed procedures and alternative approaches to achieve aims.

Significance and Relevance of the proposed research to IBD (Crohn's disease and/or ulcerative colitis) (1 page) Please note that Significance/Relevance to IBD is a separately scored section of the proposal and is considered very seriously to determine whether the topic of research addresses a research priority.

- Justify the significance of the results of this project to the understanding of the etiology, pathogenesis, therapy, and prevention of IBD. Specifically identify the gaps this project is intended to fill as it relates to the priorities outlined in Challenges in IBD (add link) or if not related to Challenges in IBD, why the research proposal is so compelling that it should be considered a priority for funding.
- For preclinical research, the project must demonstrate its relevance to human IBD mechanisms or explain why this should not be a priority for this particular research.

Facilities Available for Proposed Studies (one or two paragraphs)

- Describe the facilities available, including square footage, equipment, animal care facilities, and other environmental factors. Pay attention to those items required for successful completion of this proposal. Include a description for each facility to be involved.
- Sufficient information must be included to demonstrate the high quality of the PI's research, the co-investigators, available research resources and the applicant institution and its support of the project. Should particular equipment or lab space be required for the project and provided by the institution, include a letter of commitment of these resources.

Bibliographic References (3 pages)

- Literature citations should be listed in this section, at the end of the Research Plan. These are not counted as part of the 7-page limit.

Reply to Previous Review (REQUIRED for Resubmission applications ONLY) (1 page)

- For Resubmissions, upload a letter that clearly and succinctly addresses the points

raised in the previous review and direct 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

Letters of Collaboration

- Attach letters of collaboration from all senior personnel cited in the proposal but not included in the budget. The letter should be concise and confirm the participation of the collaborator in the project and in what capacity (providing samples, reviewing protocols or publications, etc.)

Applicants' CV/NIH Biosketch

Attach the CV/NIH Biosketch for the applicant. Please upload the CV/NIH Biosketch for each of the key personnel on the proposed project.

Human and/or Animal Approvals

Upload IRB approvals for human and animal research. If a protocol has not yet been approved, one will be required prior to award execution.

Appendices

Uploaded reference material may include:

- Article references
- Abstracts
- Original Pictures
- Other Letters of Support

APPLICATION FORMAT

- PI name must be clearly identified on the header of each attachment (not applicable to letters of collaboration and protocols).
- 12-point Times New Roman or 11-point Arial is the minimum font size for the text of the application. A 10-point Times New Roman or 10-point Arial font type may be used for figures, legends, and tables.
- Single-spaced text is acceptable, and space between paragraphs is recommended.
- Margins should be at least 0.5" inch all around, unless a form with different margins is supplied in the Application Templates or Forms.

SIGNATURE PAGE

A signature page signed by the applicant AND Institutional Officer is required at the time of proposal submission and must be uploaded.

SPECIAL INSTRUCTIONS FOR FOREIGN APPLICANTS

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

Please be aware that you should give more details than you might be accustomed, 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 grant@crohnscolitisfoundation.org with any questions or seeking additional information.

All materials MUST be submitted in English. Failure to comply can lead to an administrative rejection.

WHAT IF THERE ARE VALIDATION ISSUES WITH MY SUBMISSION?

If you receive a validation error for a submission, who do you contact? Contact proposalCENTRAL, following their instructions here: <https://proposalcentral.com/review/ContactUs2.asp?From=AdminModule>

REVIEW PROCESS

Peer Review of Applications

SRA applications are reviewed by the review committees, which are composed of basic and translational IBD researchers in a variety of fields. These committees generally have between 15-20 members, including leaders in their areas of expertise and 2-3 lay reviewers. In addition, ad-hoc members may be added in order to provide expertise in certain area(s), depending on the composition of topics of the submissions. Each application is assigned a primary, secondary, and lay reviewer.

Reviewers are required to prepare a written evaluation of the application, addressing the following separately scored criteria:

- Overall Impact: All research supported by the Foundation must examine research questions that have a direct application to Crohn's disease and/or ulcerative colitis, preferably with evidence that links the research question to mechanisms that are relevant to patients with IBD. It is the applicant's responsibility to explain the relevance of the proposal to human IBD or why the research should be prioritized without demonstrating this relevance.
- Significance and Challenges in IBD: The significance of the proposed studies in advancing unmet needs in IBD and how the application addresses the Challenges in IBD will be evaluated. If the application does not address at least one category of the Challenges in IBD, the case for why the research proposal is so compelling that it should be considered a priority for funding will be evaluated.
- Research Plan: This includes excellence of hypothesis, experimental design, and the likelihood of the proposed research to produce significant new information that will enhance the understanding of IBD to enable the Foundation to achieve its mission of finding cures for IBD and/or improving the quality of life of those living with these diseases.
- Excellence of Investigator and Research Environment: Investigator qualifications to be examined are scholastic background, research experience, achievements and publications. Environmental criteria include availability of appropriate space and equipment, consultants, etc.

Members of the review committees meet to discuss and select the most scientifically sound and impactful proposals. Selected proposals are scored, using a 9-point rating scale (1 = exceptional; 9 = poor) based on the above-mentioned criteria and then ranked against other submitted proposals.

Review by Grants Council

Projects in the fundable range are examined and ranked by the Grants Council in respect to the Foundation's goals, as outlined in the document, "Challenges in IBD". The link can be found here: https://academic.oup.com/ibdjournal/issue/25/Supplement_2.

Board of Trustees Approval

The Grants Council recommends the proposals for funding to the Board of Trustees, which is then responsible for making the final decision to approve funding.

STATEMENT OF COMMITTEE IMPARTIALITY

To ensure that the peer review process undertaken by the Foundation's review committees is fair

and unbiased, the following procedures are in place:

An Ad Hoc Review Committee is set up to review any of the following:

- Application submitted or sponsored by a member of one of the review committees
- Applicant mentored by a Fellowship Grant Review Committee member/chair in the last five years.
- A Senior or Clinical Research Grant Review Committee member is a key personnel with 5% or more effort listed in budget of the grant application

If a committee member answered "yes" to any of the following, that will be considered a conflict and the reviewer will not participate in the evaluation of that application.

- Are you a key personnel/collaborator on this proposal (<5% effort)?
- Have you and the applicant worked at the same institution in the last three years?
- Have you collaborated with the applicant in the last three years?
- Have you co-authored/published a publication in the last three years?
- Are you a former fellow/mentor for the applicant?
- Are you and any key personnel on the application (\geq 5% effort) currently at the same institution, collaborating, and/or in a fellow/mentor relationship?
- Do you have any other conflicts reviewing this application?

Each committee reviewer must certify that to the best of his or her knowledge he/she has disclosed all conflicts of interest that he or she may have with the applications; he or she fully understands the confidential nature of the review process and agrees to the following:

- To destroy or return all materials related to it;
- Not to disclose or discuss the materials associated with the review, the evaluation, or the review meeting with any other individual.
- Not to disclose procurement information.
- To refer all inquiries concerning the review to the chairperson or Foundation staff.
- To review the Foundation's "Guidelines for Maintaining Research and Peer Review Integrity"

Taken together, these steps attempt to avoid conflicts of interest among members of the committee.

NOTIFICATION

An award or declination communication will be sent to the applicant informing about the application outcome. A detailed critique summarizing the committee's deliberations will also be provided to the applicant. Applications that are not funded may be revised and resubmitted within a 3 year time period from the date of the initial submission. However, only two resubmissions are allowed. Resubmitted applications will be reviewed in the same detail and compete on an equal basis with all other new applications.

REPORTING REQUIREMENTS

Progress Reports – Interim and Final

Awardees are required to submit one progress report per project year and one final scientific report summarizing the progress made toward achieving the proposed goals and outcomes.

Second and third year funding is contingent upon the favorable evaluation of the first and second years' progress reports. The final scientific report is due 90 days after the end of the project. Payments will not be processed while progress reports are delinquent.

Progress reports are due 10 months after the start date of the current year of the award. Reports should follow the template provided in proposalCENTRAL and available for download on the Foundation's website. If the report lists any publication, please include an electronic copy at the end of the report. If an electronic copy is not available, please briefly explain why.

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.

ADDITIONAL AWARD POLICIES AND REQUIREMENTS

Policy on no-cost extension

In the event the research is delayed, an extension is required and a no-cost extension request form and documentation must be e-mailed to grant@crohnscolitisfoundation.org no later than 60 days before the end of the project period. This request must be made on institutional letterhead and signed by both the PI and the Institutional Official.

Multiple no-cost extensions may be considered based on the research involved.

Please ensure that annual progress and financial reports have been uploaded in proposalCENTRAL before submitting a no-cost extension request, as requests will not be considered for awards with outstanding required reports.

The no-cost extension request form and instructions are available on the Foundation's website.

Policy on publications and award acknowledgment

Publications resulting from research activities supported by the Foundation should contain the following acknowledgement:

Supported by the Crohn's & Colitis Foundation, award number xxxxxx, project title xxxxx.

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.

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.

Policy on patents and intellectual property

It is understood that submission of a proposal for funding consideration indicates that both PI and Institution are informed of and agree with the Foundation's Patent and Intellectual Property Policy, available for download on the Foundation's website.

Policy on award transfer

Recipients may transfer their grant from one institution to another. Projects that have been funded for

six months or longer will be reviewed by an administrative committee after full details of the new environment and budget have been provided.

The change of institution request form and instructions are available on the Foundation's website or contact grant@crohnscolitisfoundation.org.

Policy on carryforward

Carryforward into the next budget year is allowed up to 30% of the annual budget.

Carryforward requests for amounts above this threshold will be considered on a case-by-case basis and must be requested in writing to the Foundation staff no later than 60 days before the end of the budget period. This request must be made on institutional letterhead and signed by both the PI and the Institutional Official.

Policy on return of funds

Unspent balances at the end of the project of up to \$100 (one hundred dollars) can remain at the awardee institution and be allocated to support the PI's research efforts.

Unspent balances at the end of the project of more than \$100 (one hundred dollars) must be returned in full to the Foundation.

Withdrawal of Application

Applicants are asked to notify the Foundation in writing should they decide to withdraw their applications for any reason.

Change of Address

Applicants are responsible for notifying the Foundation in writing of any changes of address, email or phone number, following the submission of an application.