LITWIN IBD PIONEERS PROGRAM

INSTRUCTIONS AND POLICIES

Effective May 2019

Crohn's & Colitis Foundation National Office
Research & Scientific Programs Department
733 Third Avenue, Suite 510
New York, NY 10017

Phone: 646-943-7505
Web site: http://www.crohnscolitisfoundation.org
E-mail: grant@crohnscolitisfoundation.org

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

INTRODUCTION AND SOURCE OF FUNDS

The Crohn's & Colitis Foundation (the Foundation) was established in 1967 to find the cause of and cure for Crohn's disease and ulcerative colitis, collectively known as inflammatory bowel diseases (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 biomedical and clinical sciences, which is likely to increase our understanding of the etiology, pathogenesis, therapy, and prevention of inflammatory bowel diseases. Collaborative efforts between basic scientists and clinicians are encouraged.

Each year, the Foundation receives approximately hundreds of requests for research support. All proposals are subjected to multiple levels of peer review that identify the most meritorious and innovative projects for funding.

SCOPE & OBJECTIVES

The objective of the Litwin IBD Pioneers Research Award is to help persons with inflammatory bowel diseases by supporting innovative, early-stage research that opens new avenues for diagnosis, therapy, and prevention of these diseases. The program will consider funding clinical or translational IBD research projects that:

- Are innovative;
- Are in the early stages of exploration; and
- Have the potential to improve diagnosis, therapy, management, or prevention of IBD and their complications.

Proposals must be clinically relevant and must have the potential to benefit patients with IBD. The program is designed to support research that can be readily translated to improve the care of human IBD in the near future. Examples of projects include, but are not limited to clinical trials; observational clinical studies; biomarker identification; and evaluation of novel therapeutic modalities. Proposals related to translational science should have clear relevance to findings and observations in IBD patients. Proposals relating to investigation of basic disease mechanisms in animal models or *in vitro* systems are not typically prioritized under this mechanism; applicants may consider other Foundation programs, such as the Senior Research Award program, for such projects.

All applicants for Foundation funding should take into account the current research priorities of the organization, as described in a comprehensive document, Challenges in IBD Research. These priorities are revised every 5 years based on input from leaders in the IBD research community and additional stakeholders including IBD patients. The most current Challenges in IBD document can be accessed using the following link: https://academic.oup.com/ibdjournal/issue/25/Supplement_2

PROJECT FUNDING & DURATION

Projects may be proposed with an expected duration of 1-2 years. However, awards are initially made only for the first year of the project. If a PI wishes to seek continuation funding, PI may apply for a second year of funding (renewal); awarding of second year funding will be competitive and based on evaluation of progress toward milestones initially projected for the first year of the project.

Budgets should be appropriate for the project's scope of work and resources necessary to complete the goals. All necessary costs for conduct of the study can be budgeted, including items such as personnel, supplies, equipment, publications costs, and travel. There is no fixed upper or lower limit of funding, but awards are generally not funded above $130,000 per year, including 10% indirect costs, for clinical studies (including studies involving clinical sample analysis); and above $110,000, including 10% indirect costs, for laboratory-based studies. Indirect costs cannot exceed 10% of total costs. Thus, if the applicant is successful in obtaining the initial award (for year 1 activities) and a renewal award, the maximum total funding for the project would be $260,000. No further continuation of funding will be considered beyond the first renewal award.

APPLICANT ELIGIBILITY

1. The applicant institution must be a non-profit, charitable institution, such as a university, hospital, or research organization. Applications are accepted from institutions worldwide.
2. The applicant who wishes to take on the Principal Investigator position must have a faculty appointment at the institution. For this reason, we request that the applicant's university or institution (particularly the Grants and Contracts personnel) send us a statement confirming that the applicant is or is not able to apply as a Principal Investigator from his/her institution.
3. There can be only one Principal Investigator for each proposal.

Eligibility is not restricted by citizenship or geography.

PROPOSAL ELIGIBILITY & RESTRICTIONS

- Only one proposal may be submitted for this award per submission date.
- Applicants for Litwin award may not simultaneously submit another application focused on the same research topic for another Foundation funding program.
- The submitted research proposal must be in the field of inflammatory bowel diseases.

COMPLETING THE APPLICATION

Submission Process

The Foundation uses the proposalCENTRAL system for all of its application submissions. To access submission forms, navigate to: https://proposalcentral.com

Select the “Grant Opportunities” tab and select “Crohn’s & Colitis Foundation”.

Each applicant needs to submit a Letter of Intent (LOI) prior to sending a full application. The LOI is reviewed competitively and only those approved are invited to submit a full application. **The letter of intent is mandatory for all new applications.** Resubmissions do not require a letter of intent.

If your LOI is approved, you will receive an e-mail and will be able to access the full proposal submission form in ProposalCENTRAL. Critiques of the LOI will be provided; applicants are encouraged to consider these critiques when preparing the full proposal. Applications should be submitted on proposalCENTRAL by the due dates indicated below. You will also be notified if an LOI is declined or if a revised application is requested.

If you have questions regarding the electronic process, contact the Foundation by phone at 646-943-7505 or via email at grant@crohnscolitisfoundation.org.

Application Timetable

	Spring review cycle	**Fall review cycle**
LOI deadline	November 5th, 5:00 pm EST*	May 20th, 5:00 pm EST*
LOI review decision	December	June
Full proposal deadline	January 28th, 5:00 pm EST*	July 20th, 5:00 pm EST*
Funding notification for funded projects	July	January

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

Contact Information
For any questions or concerns please contact the Foundation grants office:
Telephone: 646-943-7505; Email: grant@crohnscolitisfoundation.org.

Please note that there may be a delay in responses close to the application deadlines due to the high number of applicant inquiries.

LETTER OF INTENT
(Stage 1 of the application process)

Each applicant must submit a letter of intent (LOI) prior to submitting a full proposal for consideration. LOIs are reviewed by committee and selected on a competitive basis. LOIs that do not address the program criteria will be rejected. 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 in a given cycle need to inform the Foundation by the respective 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, PI email address, 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.

Reviewers of the Letters of Intent are asked to evaluate the LOI and to provide a brief critique regarding:

1. Scientific merit
2. Alignment with Litwin program objectives
3. Principal Investigator qualifications and scientific environment

LOI form sections are described below. Please complete the LOI online in proposalCENTRAL and adhere to the character limitations of each section and the other requirements as outlined.

- Project title. Do not use abbreviations.
- Type of Disease -Select one of the following
  - Crohn's Disease
  - Ulcerative Colitis
- Type of Research - Select one of the following
  - Basic
  - Translational
  - Clinical (Please see section on Special Instructions for Clinical Trials, if applicable)
- Challenges Priority: Please check one or more of the Challenges priority areas that is addressed by your project. (For more information about Challenges, see Scope section above.) 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.

- Estimated total requested budget for activities to be completed in the first year. (See Budget section.)
- Indicate if the application is a resubmission.
- 3 keywords.
- Enable other users to access this application. You can designate colleagues and allow them to access and manage the application here.
- Applicant/PI (Principal Investigator): 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.
- Institution & Institutional Contacts. 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, affiliations & email addresses for all senior personnel and collaborators. This is important in order to avoid conflicts of interest during review.
- 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. Maximum 3000 characters.
- 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. (For more information about Challenges in IBD, please see Scope section above.) 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 innovative that it should be considered a priority for funding despite not being described as a priority in that document. For Litwin applicants, this section should also address why the proposal is innovative and has clinical or translational relevance. Scoring will be negatively impacted if the LOI does not address these areas. Maximum 3000 characters.
- Attachments: Please upload the following to this section:
    - PI biosketch/CV
    - Description of project including specific objectives (up to 3 pages)

FULL PROPOSAL
(Stage 2 of the application process)

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.

Clinical trials requiring Foundation support in addition to outside support will be considered. Please see section on Special Instructions for Clinical Trials, if applicable.

Additionally, 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.

Each section of the online application is listed below:

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

Challenges Priority
Donors frequently have an interest in funding particular types of IBD research. Please check one Priority Area that is addressed by your project.

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 PI can be indicated as the main point of contact.

Organization Information
This is the location of where the lead PI is located and where the study will take place.

INSTITUTION AND CONTACTS Grant Administration Information
In the event an award is made, provide the name and address of the person, at the grantee institution, who will administer the grant.

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

SUMMARY

Lay Abstract/General Audience Summary
Your lay summary should be a clear, concise overview in simplified language, appropriate for non-scientific reviewers. You need to provide enough essential information that the stakeholder reviewers will be able to evaluate your application. The lay summary should include the following information:

- What question will this project attempt to answer?
- Why is this question important to IBD?
- What is the study design?
- How do the hypothesis and specific aims fit with the Foundation's scientific priorities?
- Will this research, if successful, improve the care of human IBD, in the near future? If so, how will this project do so?

Also include a brief glossary of any scientific terms included in your lay summary. Space limitation 1/2 page.

Scientific Summary of Project
The Scientific Summary should provide a clear, concise overview of the proposed work, including the background, objective, or hypothesis and its supporting rationale; specific aims of the study for general scientific audience. Space limitation 1/2 page.

Relevance of the Project to IBD
Provide a description of how this project is explicitly clinically relevant, benefiting patients with IBD, and readily translatable to improve the care of human IBD in the near future. Space limitation 1/2 page.

The above three sections will be evaluated as part of your application as well as used to inform the Foundation's National Board of Trustees and the general public of the nature of this work; therefore, do not include proprietary or confidential information.

BUGET PERIOD DETAIL

Project Start Date
Include the date on which you expect to start this project. Funded applications for the spring cycle would begin on July 1. Funded applications in the fall cycle would begin on January 1 of the following year.

Estimated Length of Project
How long it will take you to complete the work. Funding can be requested for up to two years, but grants are funded only one year at a time. If a PI wishes to seek continuation funding for one additional year, funding for a second year is competitively reviewed based upon a satisfactory Progress Report and degree to which the first year research activities reached the individualized milestones established for the project, which are provided in the award letter.

Percentage Estimation of Amount of Time Allocated to this Project
Describe how your time (in percentages) is allocated in your current position at this institution.

Percentage of Fringe Benefits Paid by Your Institution
What is the percentage (of your salary) paid by your institution for fringe benefits, such as medical insurance, etc.

Detailed Budget Pages for Year 1 only ** Required ******
Budgets should be appropriate for the project's scope of work and absolute needs. All necessary costs for conduct of the study can be budgeted, including items such as personnel, supplies, equipment, publications costs and travel. The Crohn's & Colitis Foundation adheres to the NIH salary cap limits. There is no fixed upper or lower limit of funding, but awards are generally not funded above $130,000, including 10% indirect costs, for clinical trials, and $110,000, inclusive of 10% indirect costs, for laboratory- based studies.

Complete the e-form total budget for first year.
- PI Title of Position- His or her official title at institution
- PI Direct Costs
- PI Indirect Costs

BUDGET SUMMARY AND JUSTIFICATION
Please provide justification as to the amount of support requested.

CURRENT AND PENDING SUPPORT
Current Financial Support
If you have current financial support for this project, type into the text box the name of the institute/group that funds this research.

Pending Applications
If you do not have any current pending applications please leave blank.

If you do have current pending applications, type in the title of the award(s) and the name of the agency from which you are awaiting a response. In the attachment section, attach an abstract for each application you list in this section.

It is the policy of the Crohn's & Colitis Foundation not to fund projects that are supported all or in part by another agency. This means that projects are considered to overlap if there are any shared Specific Aims or areas of budgetary overlap or percent of effort dedicated to the other project. The Peer Review Committee will make the final decision regarding any questions of overlap. The only exceptions are: institutional support. Upload as an attachment in the "Evidential Enclosure" a description of any institutional support provided by

your institution. 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 Peer 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 prior to the start date of award. Indicate with "Yes" or "No" response. If yes, indicate date of approval and attach approval in that Attachments Section, if available.

Copies of the IRB approval should be provided to the Foundation Research Department. If approval is not available at the time of application, provide a date of anticipated approval. All required assurances must be received before the start date of the approved grant.

ATTACHMENTS

Research Plan/Protocol* Required

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 6 pages, single spaced. The lengths indicated below are included as a guideline and not required. Applications exceeding the page limit may not be reviewed.

1. Overall Objectives (one or two paragraphs)

• Briefly outline the general scientific objectives

2. Specific aims (no more than 1/2 page)

• Describe concisely and realistically what the specific research described in this application is intended to accomplish. Specifically outline aims for year 1 and year 2 (if applicable), and goals, deliverables, and timelines. State any hypotheses to be tested.

3. 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). Preliminary data are not required for an application submission.

• If this is a renewal application, include a copy of your most recent Progress Report here (Progress Report is not counted as part of the six pages).

4. Detailed description of methods and materials to be used (no more than 3 pages)

a. Provide a detailed discussion of the experimental design, procedures, and materials to be used to accomplish the Specific Aims.

b. Describe protocols, including methods for new techniques, and explain the advantages over existing methodologies.

c. Discuss the kinds of data expected to be obtained and the means by which data will be analyzed and interpreted.

d. Justify the use of any animal models (i.e., choice of species, number used, etc.).

e. Discuss potential difficulties and/or limitations of the proposed procedures and alternative approaches to achieve aims.

5. Significance and relevance of the proposed research to Crohn's disease and/or ulcerative colitis (no more than 1/2 page)

• Justify the significance of the results of this project to advancing IBD diagnosis, therapy, or prevention. Specifically identify the gaps and/or pioneering approaches this project is intended to fill.

6. Facilities Available to carry out the Proposed Studies (one or two paragraphs - not included in overall 6 page limit)

• Describe the facilities available, including square footage, equipment, animal care facilities, and other environmental factors. Pay particular attention to those items required for successful completion of this proposal. Include a description for each facility to be involved.

• Pertinent References Literature citations should be listed in this section, at the end of the Research Plan. ***These are not counted as part of the 6-page limit.

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

- Please remember to insert your name in the header on each form in the attachment section.
- Font size: Use 12-point Times New Roman or 11-point Arial as 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: The margins of your text should be at least 1" all around, unless a form with different margins is supplied in the Application Templates or Forms.

Resubmission Material *Required if a Resubmission
Please follow these guidelines when resubmitting an application:

- "Reply to Previous Review", letter not to exceed three pages. The letter should clearly and succinctly address 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 (e.g.: bold type, line in the margin, underlined, etc.). A one-page summary of how the revised application addresses the primary concerns of the review should be included as the first page of the scientific portion. This page does not count against the 6 page space limitation of the text.

Include copies of the following:

- Critiques (Summary Statement) of the original application
- Budget pages of previous application
- Overall objectives and Specific Aims of previous application

Previously submitted material is not considered part of the three-page resubmission material limit.

Letters of Collaboration
Attach supporting letter(s).

Applicants' CV or NIH Biosketch *Required
Attach the CV or NIH Biosketch for the applicant. Limit CV to 10 pages. A five-page NIH Biosketch is preferred.

References/ Appendices - Optional (part of Attachments section)
Uploaded reference material may include, but not limited to:

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

Human and/or Animal Approvals - Optional
Upload IRB approvals for human and animal research, if available.

VALIDATE AND SIGNATURE PAGE
Once the application is validated, you can submit the application. The signature page is not required by the Foundation and should be printed only if you desire for your personal records.

SPECIAL INSTRUCTIONS
Applicants falling into any of the following categories should read the "Special Instructions" section pertaining to them before attempting to complete the application:

- Foreign Applicants
- Clinical Trials

Special Instructions for Foreign Applicants

- Complete budget request must be in U.S. dollars - We will NOT convert.
- 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 and budgetary items (in particular, percent of effort and salary requests for key personnel).

***ALL MATERIALS AND REPORTS MUST BE IN ENGLISH. FAILURE TO DO SO WILL RESULT IN A REJECTED APPLICATION.

Special Instructions for Clinical Trials
The Research Plan will need to include everything required in the Application Preparation section, plus the following information:

Specific Aims:
These should include a delineation of the primary and secondary end points to be measured with an appropriate explanation of the relative importance of the various end points.

Significance:
The application should clearly state the need for the study and how the results would impact on the prevailing practice in this area.

Experimental Design and Method:
The inclusion and exclusion criteria should be listed, and the procedure(s) to be utilized for assignment of patients to experimental groups should be described. The study design for the interventions to be used should be presented in detail including the rationale for the particular design chosen and procedures to assure compliance with and implementation of the proposed protocol. 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. Finally, assumptions and calculations to arrive at the proposed sample size should be included.

The availability of patients for the proposed study, including the specific characteristics that are required for the group should be presented. Approaches should be outlined that will be used for the recruitment, retention, and follow-up of the required number of patients. Data should be presented supporting recruitment and retention estimates. Plans should be described for patient protection, including informed consent, monitoring of data for safety, and early termination, as required. Appropriate informed consent forms from all participating groups (centers) should be included as an attachment, not subject to space restrictions. Projected rates of patient enrollment should be included. If enrollment falls behind projected levels, funding may be delayed or terminated.

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, 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. The 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, as specified by the National Institutes of Health Office for Human Research Protections, US Department of Health and Human Services. These policies apply to applicants and applicant institutions as well. Finally, a timetable for completion of the various phases of the trial should be presented.

A procedure or plan for data management should 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.

Evidential Enclosures:
Enclose letters of commitment from each participating center, signed by the cooperating investigator and business official. In addition, informed consent forms and evidence of Human Studies approval from all participating centers should be included in this section.

Curriculum Vitae:
Biographical sketches of all key investigators, center directors, and multidisciplinary team members should be included.

Facilities:
Clinical, data management, and laboratory facilities should be described in detail for all participating institutions, where applicable.

Budget:
A total overall budget and a complete justified budget for each year of support should be presented. This program is designed for pilot grants that have a maximum of two years support. If the trial is designed for more than the two-year period, complete justified budgets for the future years and a plan for securing funding for additional year(s) must be included. If the study involves multiple centers, a composite matrix should be submitted, where applicable. If parts of the costs of the total trial are to be provided by sources other than the Foundation, these contributions should be presented in detail along with supporting letters from appropriate and responsible individuals. Additional budget information will need to be submitted as attachment(s). These forms need to completed and uploaded in the attachment section provided. The forms can be found in the form section of the Foundation web site.

REVIEW PROCESS

1. **Review of LOIs**

LOIs are reviewed upon submission for innovation, conformity with the goals of the program and potential scientific and clinical impact. If approved for full proposal application, suggestions to improve the application may be included.

2. **Peer Review of Applications**

The Litwin IPB Pioneers award applications are reviewed by a grants review committee. The review committee is composed of basic, translational, clinical IBD researchers and lay stakeholders from a variety of fields. The committee generally has between 15-20 members; leaders in their areas of expertise and several stakeholder 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 and secondary reviewer (and when necessary, a tertiary reviewer). Many members of the review committee have held this award in previous years.

Reviewers are required to prepare a written evaluation of the application, addressing the following Selection Criteria:

- Overall Impact: All research supported by the Foundation must examine aspects of and have a direct application to Crohn's disease and/or ulcerative colitis. It is the applicant's responsibility to explain the relevance and innovation of the proposal to IBD and specifically to the Litwin IBD Pioneer objectives and the Foundation's Challenge Area priorities.
- Research Plan: This includes excellence of hypothesis, experimental design, and the likelihood of the proposed research to produce significant new information that will improve management of IBD patients.
- Excellence of Investigator and Research Environment: Investigator qualifications to be examined are scholastic background, research experience, achievements and publications, as well as their potential to successfully accomplish the aims of the proposal. Environmental criteria include availability of appropriate space and equipment, consultants, etc.

Members of the review committee meet to discuss and vote to either discuss or not discuss the application. If approved, the application is then ranked by each committee member, using a scoring system identical to that previously used by the National Institutes of Health: 1.0 being the highest ranking and 9.0 the lowest.

3. Review by Grants Council

Those 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" (see Scope section above).

4. Board of Trustees Approval

Following the Grants Council meeting, the Chief Scientific Officer of the Foundation presents the Grant Council's recommendations for funding at the next meeting of Board of Trustees. The Foundation's Board of Trustees, with input from the National Treasurer and President regarding budgetary constraints for the fiscal year, then approves the payment of grants.

STATEMENT OF COMMITTEE IMPARTIALITY

To ensure that the peer review process undertaken by the Foundation's grants review committees is fair and unbiased, the following procedures are in place:

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

- Application submitted or supported by a Litwin IBP Pioneers Committee member or their trainees.
- The Applicant mentored by a Litwin IBD Pioneers Grant Review Committee member/chair in the last five years.
- Are you a key personnel/collaborator on this proposal?

2. If a member of committee answered "yes" to any of the following, it is considered a conflict and must not participate in the evaluation of that application (MUST leave the room).

- 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 member 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 "Guidelines for Maintaining Research and Peer Review Integrity"

Taken together, these steps attempt to avoid any obvious conflicts of interest among members of the committee. For full information regarding the peer review integrity policy of the Crohn's & Colitis Foundation, please refer to the policy at the following link: https://www.crohnscolitisfoundation.org/science-and-professionals/research/pdfs/guidelines-for-maintaining.pdf

NOTIFICATION

An award notification or rejection letter will be sent to the applicant advising him/her of funding or non-funding. 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. 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 (see instructions for resubmissions.) The award letter will include individualized milestones for the award that will outline progress toward the goals and Aims that are necessary for second year renewal.

ADDITIONAL AWARD POLICIES AND REPORTING REQUIREMENTS

Final Scientific Report

The final Scientific Report, a brief summary of progress toward the achievement of originally stated aims, is due 90 days after the end of the project.

Financial Reports

Annual financial reports will be due three months after the end of each project year. For example, annual finance reports for awards beginning on January 1 will be due on April 1. Annual financial reports for awards beginning on July 1, will be due on October 1. Annual reports should contain the all expenditures from the previous year. The final financial report will include all expenditures for the entire length of the project. Please use template provided via proposalCENTRAL.

Signatures of the Principal Investigator and the institution's financial officer are required on this report. Any unexpended funds must be returned to the Foundation upon termination of the project. Final payment will be held until receipt and approval of final reports.

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.

Payment Schedule

Payments will commence after award execution. The first payment of the year one budget (50% of the budget period award) will be released once the award is activated. The second payment (the remaining 50%) will be made six (6) months later. Year two payments will follow the same payment schedule after the receipt and approval of the annual progress report. Year three payments will follow upon satisfactory approval of the annual progress report. Year three payments will begin with 50% of the award paid initially, 30% of the budget period released after six (6) months and the final 20% will be released upon approval of the final progress reports. Budget changes recommended by the review committee, if any, are included within the award letter.

Payments may be made via electronic transfer. Acknowledgement of payment by the grantee institution is not required. We require a banking letter from the awarded institution at time of acceptance.

Personnel compensated in whole or part with funds from the Foundation are not considered employees of the Foundation. Institutions are responsible for issuing the appropriate IRS tax filings for all individuals receiving compensation from the Foundation and are responsible for withholding and paying all required federal, state, and local taxes with regards to such compensation. Thus, these and any other tax consequences are the responsibility of the individual recipient and grantee institution.

Institutions must maintain separate accounts for each grant, with substantiating invoices available for audit by representatives of the Foundation. The Foundation is not responsible for expenditures made prior to the start date of the grant, or if the complete budget is expended prior to quarterly payments or any expenditures that exceed the total amount of the award. The Foundation will follow the payment schedule outlined in the award letter. Please refrain from sending invoices to the Foundation from the institution as these will not be paid in the manner they are received.

The Foundation research grants are not designed to cover the total cost of the research proposed nor the investigator's entire compensation. The grantee's institution is expected to provide the required physical facilities and administrative services normally available in an institution.

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.

Request for leave will be handled on a case-by-case basis.

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. Awards are made with the understanding that the Foundation will receive written notification of the filing of any letters of patent for any discovery made based on work funded by the Foundation.

THE FOUNDATION PATENT AND INTELLECTUAL PROPERTY 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.

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 administratively reviewed 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.

Required:

A. Written authorization from the Signing Official at the new institution accepting the award
B. Letter of release from present institution relinquishing the award
C. Updated Address of PI and Organization
D. Signature page with PI and Institutional Official Signatures
E. Full details of the new environment and budget
F. New personnel – names, time spent on the award
G. Description of any changes to the original protocol
H. IRB certificate/research consent forms if applicable
I. A financial accounting from the present institution within 30 days of the transfer

All the above documents must be received and approved by the Foundation before the award can be transferred. An official letter will be sent to the awardee as soon as all transactions concerning this transfer have been completed.

Payments to the new institution will not be sent until a final accounting and a check for any unexpended funds have been received from the original institution and the transfer has been approved by the foundation.

Withdrawal of Application
Please advise the Foundation promptly, in writing, should you decide to withdraw your application for any reason. Your letter should include your name, type of award, project title, reference number, and reason for withdrawal.

Change of Address
Notify the Foundation in writing of any changes of address, email or phone number, following the submission of an application.

For more post-award policies and requirements, please visit the Foundation's website or send an email:

Website: http://www.crohnscolitsfoundation.org
Email: grant@crohnscolitisfoundation.org