

# Career Development Award

# APPLICATION INSTRUCTION MANUAL

Crohn's & Colitis Foundation

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

General Submission Inquiries: <a href="mailto:training\_awards@crohnscolitisfoundation.org">training\_awards@crohnscolitisfoundation.org</a>



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# Introduction

The Crohn's & Colitis Foundation (the Foundation) was established in 1967 to find the causes of and cures for Crohn's disease and ulcerative colitis, collectively known as inflammatory bowel disease (IBD.) Support for our research program is provided by volunteers and donors, as well as 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 IBD disease interception, restoration of function from the cellular level to quality of life, and remission to prevent relapse and disease progression. Mechanisms in IBD that are demonstrably relevant to the human disease are particularly important as a focus for preclinical research.

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

The goal of **the Career Development Award (CDA)** is to encourage a career of independent basic and/or translational investigation in the area of Crohn's disease and ulcerative colitis research. Therefore, individuals who are already well established in the field of IBD research are not considered eligible for this award.

#### **Opportunity for Foundation Awardees to Access IBD Plexus**

The Crohn's & Colitis Foundation is pleased to inform researchers applying for its Career Development Award (CDA) that they may gain access at no cost to the biosamples and/or research-ready datasets housed within IBD Plexus as part of a newly funded CDA research project. IBD Plexus<sup>™</sup> was founded by the Foundation with a mission to advance science, accelerate progress towards precision medicine and improve the care of patients living with IBD. The multi-component IBD Plexus includes a biobank, pediatric and adult patient clinical data, patient-reported data, linked genetic and other molecular data and biosamples, central reference labs to generate molecular data (genetic, transcriptomic, microbiomic, etc.) from existing biosamples, as well as a data and analytical platform to house, organize, aggregate, and provide data for research.

Investigators who choose to convert biosamples to molecular data as part of their research proposal can use CDA funds to help defray those costs. Most molecular data generation is done at IBD Plexus central reference laboratories to promote standardization and the ability to pool results. Further, IBD Plexus functions under the guiding principle that researchers who take advantage of the resources will also contribute back the raw data (not the analyses) they derive from patient biosamples.

For more details about IBD Plexus data and samples, please review the <u>high-level overview</u>, summary, and <u>data/sample use agreements</u>.

#### Crohn's & Colitis Foundation/NASPGHAN IBD Young Investigator Awardee

A single awardee for the annual Crohn's & Colitis Foundation/NASPGHAN IBD Young Investigator Award is chosen in late June/early July from both the Fall and Spring cycles.

This three-year grant, in partnership with the NASPGHAN Foundation and the Crohn's & Colitis Foundation, is available to research fellows or junior faculty. Applications must propose original basic or translational scientific research related to pediatric IBD. Applicants must indicate that their submission is pediatric IBD-related to be considered for this award.

# Eligibility

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.

## Applicant Eligibility

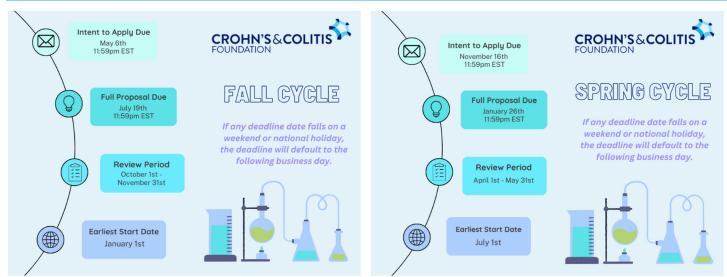
At the time of application, the applicant must:

- 1. Hold an MD, PhD, or equivalent terminal degree.
  - a. Candidates who hold an M.D, must have **at least three years** of post-doctoral experience prior to the application deadline, and two years of which must encompass research directly relevant to IBD.
  - b. Candidates holding Ph.D. degrees must have **at least two years** of documented post-doctoral research experience relevant to IBD prior to the application deadline.
- 2. Be employed by an institution (public non-profit, private non-profit, or government) engaged in healthcare and/or health related research.
- 3. Eligibility is not restricted by citizenship, however, proof of legal work status in the United States is required.

#### 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 a CDA may not simultaneously apply for another award (Research Fellowship or Senior Research).
- 4. Applicants for a CDA may not simultaneously submit another application focused on the same research topic for a Litwin IBD Pioneer Award or Research Initiative.
- 5. Applicants may not hold concurrent Foundation CDAs; however, applications for new projects may be submitted 6 months prior to the termination of an awardee's current grant.

# **Application Process**



## Intent to Apply

Each applicant must complete the Intent to Apply (ITA) form prior to submitting a full proposal for consideration. This form is reviewed seriously by the Grants team, which determines if the applicant is invited to submit a full proposal. Each section of the form should be completed fully to be eligible for funding consideration. Use the following outline to guide you through completing the ITA form.

## Components of Intent to Apply

Please complete the ITA form online in ProposalCentral and adhere to all character limits and other requirements as outlined.

#### 1. INTENT TO APPLY

#### 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

- Please check one of the
  "<u>Challenges in IBD</u>" priority areas that will be addressed by your project.
- ii. 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.



iii. Link to the Challenge priority areas can be found here.

#### c. Type of Disease

i. 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.
  - 1. Note: If your study is clinical research based, please refer to our new clinical research <u>opportunities</u>.

#### e. Resubmission

i. Use the dropdown menu to indicate if this will be a resubmission of a previous application.

#### 2. APPLICANT/PRINCIPAL INVESTIGATOR (PI) INFORMATION

- a. Pl 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.

#### 3. 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.

#### 4. ELIGIBILITY QUIZ

- a. Answer the questions in this section to determine your eligibility for the grant, which will enable you to continue with the application process.
  - i. Note: Please read these questions carefully and respond truthfully and accurately.

#### 5. INSTITUTION AND INSTITUTIONAL CONTACTS

- a. Identify your institution and input basic contact information.
- b. Add institutional contacts.
  - i. You will be required to have an institutional official sign your Intent to Apply form, so make sure to add them as a "Signing Official" in this section.

#### 6. ENABLE OTHER USERS TO ACCESS THIS PROPOSAL

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

#### i. A contact that will sign your Intent to Apply form must be added.

#### 7. SUMMARY PAGE

- a. Use this section to provide a short summary of your proposed research project.
- b. The summary should provide a clear overview of the proposed work.

#### 8. VALIDATION PAGE

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

#### 9. SIGNATURE PAGE

a. In this section, both you and a signing official must digitally sign the form to indicate it is complete and accurate.

#### **10. 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.

#### **11. FUNDING OPPORTUNITIES**

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

# Application

After ITAs are reviewed, selected applicants will be informed if their proposals have been selected for full application submission. There is an approximate three-week turnaround on ITA decisions after the deadline has occurred.

# Components of Full Application

#### 1. TITLE PAGE

- a. <u>Project Title</u>
  - i. Fill in project title. If this is a resubmission, the title should be the same as the original application.
- b. <u>Type of Research</u>
  - i. Basic
  - ii. Translational
  - iii. If your study is clinical research based, please see our <u>new clinical research</u> <u>opportunity</u>.
- c. <u>Challenges Priority</u>
  - i. Please check one priority area that is addressed by your project, or if your project is not related to Challenges in IBD, describe why the research proposal is so compelling that it should be considered a priority for funding.
  - ii. If it is a proposal for preclinical research, then the project must demonstrate its relevance to human IBD mechanisms, such as evidence of reverse translation (from bedside to bench), use of disease models reflecting human disease, validation in human samples, etc.
- d. <u>Type of Disease</u>
  - i. Select one of the following:
    - 1. Crohn's disease
    - 2. Ulcerative colitis
    - 3. Inflammatory Bowel Disease non-specified

#### 2. APPLICANT (PI)

- a. Principal Investigator
  - i. 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.
  - ii. While a project can have mentors and co-mentors, only one person at the awardee's organization can be the point of contact responsible for technical and financial management of the award, as well as the award's scientific outcomes and reports.
- b. <u>Organization Information</u>
- i. This is where the lead PI is located and where the study will take place.

#### 3. INSTITUTION AND CONTACTS

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

#### 4. KEY PERSONNEL

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

#### 5. MENTOR INFORMATION

- a. In this section, please fill out the information for the researcher who will be mentoring you on this study.
  - i. 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 Career Development Award
- b. Career Development Plan
  - i. The PI is asked to submit a < 3-page career development plan to include a description of the career development research need, activities, milestones, and timeline, which should align with the plan described in the mentor's letter of support.

#### 6. LAY SUMMARY

- a. 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:
  - i. What question will this project attempt to answer?
  - ii. Why is this question important to IBD?
    - 1. How would the results significantly advance the field of IBD research or impact patient care or quality of life?
  - iii. How does the research address the Challenges in IBD?
    - 1. Or, if not related to Challenges in IBD, why is the research proposal is so compelling that it should be considered a priority for funding?
  - iv. What is the study design? How is it innovative?
  - v. How do the hypothesis and specific aims fit with the Foundation's scientific priorities?
  - vi. If the research is successful, what next steps would be needed to advance the Foundation's mission to find cures for IBD and/or to improve quality of life for IBD patients?
- b. In addition, include a brief glossary of any scientific terms included in your lay summary.
- c. This section 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.

#### 7. SCIENTIFIC SUMMARY

- a. 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.
- b. Relevance of the Project to IBD
  - i. Provide a description of how this project is explicitly related to IBD and how it will further research to achieve the Foundation's mission.
    - 1. 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 research.
      - a. Examples: Provide evidence of reverse translation (from bedside to bench), use of disease models reflecting human disease, validation in human samples, etc.
- c. This section 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.

#### 8. BUDGET

- a. <u>Project Start Date</u>
  - i. Date on which you expect to start this project.
    - 1. Funded applications for the Spring cycle would begin on July 1st.
    - 2. Funded applications in the Fall cycle would begin on January 1st of the following year.
- b. Estimated Length of Project
  - i. CDA projects can range from 12 to 36 months duration.
- c. <u>Percentage Effort</u>
  - i. Describe how your time (in percentages) is allocated in your current institutional position.
    - 1. Career Development Award recipients are required to dedicate at least 65% of their time to the Foundation's funded project.
    - 2. This breakdown includes your research duties, clinical duties, teaching duties and any other tasks required by your institution.
    - 3. An institutional representative will be required to confirm this information as part of the proposal submission process.
- d. <u>Detailed Budget</u>
  - i. The total budget can be requested for up to three years.
  - ii. The request per year may not exceed \$102,500.
    - 1. The salary request cannot exceed \$60,000/year.
    - 2. Fringe benefit requests cannot exceed 25% of salary or up to \$15,000 per year.
    - 3. Non-salary/non-fringe requests cannot exceed \$27,500.
    - 4. Indirect costs are not awarded for an CDA.
  - iii. Salaries may be supplemented by the applicant's institution.
  - iv. A travel budget should be included to attend the Crohn's & Colitis Congress (in years one and three), which is usually held annually in January.
    - 1. Additionally, in the second year of the award, there must be set aside a travel budget to attend the Foundation Researcher Symposium, which is held near New York City.
- e. <u>Budget Justification</u>
  - i. It is the applicant's responsibility to justify the budget.
  - ii. Items not adequately justified will not be supported.
  - iii. Please provide a budget justification for the amount requested.
  - iv. 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.

#### 9. CURRENT AND PENDING SUPPORT

- a. Provide information on currently active projects and proposals pending review.
- b. For pending applications, attach an abstract for each application you list in this section as an appendix in the Attachments Section.
  - i. Scientific Funding and Overlap
    - 1. The Crohn's & Colitis Foundation reserves the right not to fund projects that are supported completely or in part by another agency.
    - 2. 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.
    - 3. The review committee will make the final decision regarding any questions of overlap.

- ii. Evidential Enclosure
  - 1. There is an exception for institutional support (PI faculty package, discretionary funds, etc.)
    - a. 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.
  - 2. If this is applicable to this proposal, <u>a description of any institutional support</u> <u>provided by the institution should be uploaded to the section</u> "Evidential Enclosure."
  - 3. The details should include institutional commitment to the support of the applicant's salary and the current term of the applicant's appointment.

#### **10. ORGANIZATIONAL ASSURANCES**

- b. Human/Animal Studies Approval
  - i. 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.
  - ii. This approval is required for study activation and initial payment.
  - iii. Please indicate using a "Yes" or "No" response, and if yes, indicate date of approval and upload approved protocol in the Attachments Section.

#### 11. ATTACHMENTS

#### a. Research Plan/Protocol

#### i. This section is limited to 9 pages, single spaced (1/2 inch margins.)

- ii. 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.
  - 1. The lengths indicated below are included as a guideline and not required.
  - 2. Applications exceeding the page limit will not be reviewed.
- iii. <u>Overall Objectives</u> (one or two paragraphs)
  - 1. Describe the general scientific objectives of the project.
- iv. <u>Specific Aims</u> (approximately 1 page)
  - 1. Describe concisely and realistically what the specific research described in this application is intended to accomplish.
  - 2. Specifically, outline Aims for year 1, year 2 or year 3, goals, deliverables and timelines.
  - 3. State any hypotheses to be tested.
- v. <u>Background</u> including preliminary data (approximately 2 pages)
  - 1. Outline the previous work in the area by others, and the preliminary data or previous studies by the investigator(s).
  - 2. 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.
- vi. <u>Methods and Materials</u> (approximately 5 pages)
  - 1. Provide a detailed discussion of the experimental design, procedures, and materials to be used to accomplish the Specific Aims.
  - 2. Describe protocols, including methods for new techniques, and explain the advantages over existing methodologies.
  - 3. Discuss the kinds of data expected to be obtained and the means by which data will be analyzed and interpreted.
  - 4. Justify the use of any animal models (i.e., choice of species, number used, etc.).

- 5. Discuss potential difficulties and/or limitations of the proposed procedures and alternative approaches to achieve aims.
- vii. <u>Significance and Relevance to IBD</u> (approximately 1 page)
  - 1. 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.
  - 2. Justify the significance of the results of this project to the understanding of IBD disease interception, restoration of function from the cellular level to quality of life, and remission to prevent relapse and disease progression.
    - a. Specifically identify the gaps this project is intended to fill as it relates to the priorities outlined in 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.
  - 3. For preclinical research, the project must demonstrate its relevance to human IBD mechanisms, such as evidence of reverse translation (from bedside to bench), use of disease models reflecting human disease, validation in human samples, etc., or explain why this is not be a priority for this research.
- viii. Mentor's Letter of Support
  - 1. Attach supporting letter from your mentor(s).
  - 2. This letter should include the following:
    - a. Description of the facilities and equipment available for the proposed project.
    - b. Outline of training program (i.e., courses, workshops, etc. and career development plan for the applicant.)
- ix. <u>Career Development Plan</u>
  - 1. The PI is asked to submit a < 3-page career development plan to include a description of the career development research need, activities, milestones, and timeline, which should align with the plan described in the mentor's letter of support.
- x. Institutional Letter of Support
  - 1. A letter from the applicant's Department Chairperson or authorized institutional representative which guarantees protected research time commensurate with the percentage of effort/salary to be devoted to the research project.
- xi. Letters of Collaboration
  - 1. Attach letters of collaboration from all senior personnel cited in the proposal but not included in the budget.
  - 2. Each 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.)
- xii. Applicant CV/NIH Biosketch
  - 1. Attach the CV/NIH Biosketch for the applicant.
  - 2. Please upload the CV/NIH Biosketch for each of the key personnel on the proposed project.
- xiii. Applicant Research Experience
  - 1. A documentation of the applicant's research experience.
    - a. Template is provided in ProposalCentral.
- xiv. <u>Mentor NIH Biosketch</u>
  - 1. Attach the NIH Biosketch for all mentor(s).

- xv. Additional Mentor Page (optional)
  - 1. Upload information on additional mentor(s) who are not already listed in the main application.
- xvi. <u>Human and/or Animal Approvals</u>
  - 1. Upload IRB approvals for human and animal research.
  - 2. If a protocol has not yet been approved, one will be required prior to award execution.
- xvii. <u>Proof of Work Status</u> (optional)
  - 1. Non-U.S. citizens must upload documentation that shows their proof of status to work in the United States. This may include a copy of their green card or work visa.
- xviii. <u>Reply to Previous Review</u> (approximately 1 page)
  - 1. This is required for Resubmission applications only.
  - 2. Upload a letter that clearly and succinctly addresses the points raised in the previous review (ie. Budget issues, overall objectives, etc) and direct the reviewer to the specific sections of the Research Protocol where revisions have been made.
  - 3. Revised portions of the text changed in response to the reviewers' comments should be highlighted.
- xix. Bibliographic References (approximately 3 pages)
  - 1. Note: These are not counted as part of the 9-page limit.
  - 2. Literature citations should be listed in this section, at the end of the Research Plan.
- xx. <u>Appendices</u>
  - 1. Uploaded reference material may include:
    - a. Article references
    - b. Abstracts
    - c. Original Pictures
    - d. Other Letters of Support

#### 12. APPLICATION FORMAT

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

#### 13. SIGNATURE PAGE

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

#### 14. VALIDATION ISSUES

- a. If you receive a validation error for a submission, who do you contact?
- b. Contact ProposalCentral, following their instructions <u>here</u>.

#### 15. ARTIFICIAL INTELLIGENCE DISCLAIMER

- a. The Crohn's & Colitis Foundation is committed to funding the most innovative and thorough research, with the goal that this research will ultimately contribute to curing IBD. We recognize that technology is an evolving force, and the recent Artificial Intelligence developments are commendable. However, the Foundation champions integrity and ethics, and for this reason, any use of Artificial Intelligence (natural language processors, large language models, etc.) in the scope of applying for a grant will result in disqualification of that application.
- b. This applies to submissions for both the pre-application and the full application.
- c. At the discretion of the Foundation, an exception can be made only if the technology is used to support a disability and improve accessibility for the applicant. If you have any questions about this policy, please reach out to the Grants team at grant@crohnscolitisfoundation.org.

# **Review Process**

# Peer Review of Applications

CDA applications are reviewed by committees that are composed of basic and translational IBD researchers in a variety of fields and patient/caregiver reviewers. In addition, ad-hoc members may be added to provide expertise in certain area(s), depending on the composition of topics of submissions. Each application is assigned a primary, secondary, and patient/caregiver reviewer.

## **Review Components**

#### 1. OVERALL IMPACT

- a. 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.
  - i. 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.

#### 2. SIGNIFICANCE AND CHALLENGES IN IBD

- a. The significance of the proposed studies in advancing unmet needs in IBD and how the application addressed the <u>Challenges in IBD</u> will be evaluated.
  - i. If the application does not address at least one category of the <u>Challenges in IBD</u>, the case for why the research proposal is so compelling that it should be considered a priority for funding will be evaluated.

#### 3. RESEARCH PLAN

a. This includes excellence of hypothesis, experimental design, and the likelihood of the proposed research to produce significant new information that will 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.

#### 4. EXCELLENCE OF INVESTIGATOR AND RESEARCH ENVIRONMENT

- a. Investigator qualifications to be examined are scholastic background, research experience, achievements, and publications.
  - i. Environmental criteria include availability of appropriate space and equipment, consultants, etc.

#### 5. PROCESS

- a. Members of the review committees meet to discuss and select the most scientifically sound and impactful proposals.
  - i. 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.

#### 6. REVIEW BY GRANTS COUNCIL

a. 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, "<u>Challenges in IBD</u>."

#### 7. BOARD OF TRUSTEES APPROVAL

a. 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 Research Training Review Committee 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:
  - a. Application submitted or sponsored by a member of one of the review committees.
  - b. Applicant mentored by a Research Training Review Committee member/chair in the last five years.
  - c. A Research Training Review Committee member is key personnel on the grant application.
  - d. If a committee member answers "yes" to any of the following, that will be considered a conflict and the reviewer will not participate in the evaluation of that application.
    - i. Are you a key personnel/collaborator on this proposal?
    - ii. Have you and the applicant worked at the same institution in the last three years?
    - iii. Have you collaborated with the applicant in the last three years?
    - iv. Have you co-authored/published a publication in the last three years?
    - v. Are you a former fellow/mentor for the applicant?
    - vi. Do you have any other conflicts after reviewing this application?
  - e. Each committee reviewer must certify that to the best of their knowledge that they have disclosed all conflicts of interest that they may have with the applications; and that they fully understand the confidential nature of the review process and agree to the following:
    - i. To destroy or return all related materials
    - ii. Not to disclose or discuss the materials associated with the review, the evaluation, or the review meeting with any other individual.
    - iii. Not to disclose procurement information.
    - iv. To refer all inquiries concerning the review to the chairperson or Foundation staff.
    - v. To review the Foundation's "Guidelines for Maintaining Research and Peer Review Integrity."
    - vi. 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 them about the application outcome.

- 1. A detailed critique summarizing the committee's deliberations will also be provided to the applicant.
- 2. Applications that are not funded may be revised and resubmitted within a 3-year time period from the date of the initial submission.
  - a. Resubmitted applications will be reviewed in the same detail and compete on an equal basis with all other new applications.
  - b. Only two resubmissions are allowed.

# **Reporting Requirements**

#### 1. PROGRESS REPORTS

- a. 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.
  - i. Funding for the second and third year is contingent upon the favorable evaluation of the first- and second-year progress reports.
  - ii. The final scientific report is due 90 days after the end of the project. Payments will not be processed if progress reports are delinquent.
- b. Progress reports are due 10 months after the start date of the current year of the award.
  - i. Reports should follow the template provided in ProposalCentral.
    - 1. This template is also available for download on the Foundation's website.
  - ii. If the report lists any publication, please include an electronic copy at the end of the report.
    - 1. If an electronic copy is not available, please explain why.

#### 2. FINANCIAL REPORTS

- a. Annual financial reports are due 3 months after the end of the annual budget period.
  - i. To allow for year-to-year comparison, the report should be submitted with the template provided in ProposalCentral.
  - ii. The report should be signed by a Financial Officer at the awardee's institution.
  - iii. Failure to observe these requirements may delay payment.
  - iv. Final payments will not be made for awards with delinquent deliverables.

# No-Cost Extension Policy

In the event the research is delayed, an extension is required.

- 1. A no-cost extension request form and documentation must be emailed to
  - <u>grant@crohnscolitisfoundation.org</u> no later than 60 days before the end of the project period. a. This request must be made on institutional letterhead and signed by both the PI and the
  - Institutional Official.
- 2. Multiple no-cost extensions may be considered based on the research involved.
  - a. Please ensure that annual and financial reports have been uploaded in ProposalCENTRAL before submitting a no-cost extension request.
    - i. Requests will not be considered for awards with outstanding required reports.
    - ii. The <u>No-Cost Extension Request Form</u> and instructions are available on the Foundation's website.

## **Publications Policy**

#### 1. PUBLICATIONS

- a. Publications resulting from research activities supported by the Foundation should contain the following acknowledgment:
  - i. "Supported by the Crohn's & Colitis Foundation, award number XXXXX, project title XXXXX."
- b. The Foundation's support should also be acknowledged by the awardee and by the awardee's institution in all public communication of work resulting from this grant.
  - i. This includes scientific abstracts, posters at scientific meetings, press releases/other media communications, and internet-based communications.
- c. 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 to the award record in ProposalCentral.

#### 2. PATENTS AND INTELLECTUAL PROPERTY

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

## **Post-Award Policies**

Post award policies can be found <u>here</u>.

#### 1. AWARD TRANSFER POLICY

- a. Recipients may transfer their grant from one institution to another.
- b. 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.
- c. The <u>Change of Institution Request Form</u> is available on the Foundation's website.
  - i. If help is needed, please contact grant@crohnscolititsfoundation.org

#### 2. CARRYFORWARD POLICY

- a. Carryforward into the next budget year is allowed up to 30% of the annual budget.
- b. Carryforward requests for amounts above this threshold will be considered on a case-bycase basis.
  - i. These must be requested in writing to the Foundation staff no later than 60 days before the end of the budget period.
    - 1. This request must be made on institutional letterhead and signed by both the PI and the Institutional Official.

#### 3. RETURN OF FUNDS POLICY

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

#### 4. APPLICATION WITHDRAWAL

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

#### 5. CHANGE OF PERSONAL INFORMATION

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