**CROHN'S & COLITIS FOUNDATION OF AMERICA**

# Senior Research Award

## INSTRUCTIONS AND POLICIES
**Effective June 2016**

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

**Phone: 646-943-7501**
**Web site: http://www.ccfa.org**
**E-mail: grants@ccfa.org**

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

**CONTENTS**

**INTRODUCTION AND SOURCE OF FUNDS**

The Crohn's & Colitis Foundation of America, (CCFA), 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 biomedical and clinical sciences, which is likely to increase our understanding of the etiology, pathogenesis, therapy, and prevention of the inflammatory bowel diseases. Collaborative efforts between basic scientists and clinicians are encouraged.

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

## OBJECTIVE

The objective of the Senior Research Award (SRA) is to provide established researchers with funds to generate sufficient preliminary data to become competitive for funds from other sources, such as the National Institutes of Health (NIH).

## APPLICANT ELIGIBILITY\INDEPENDENCE

At the time of application, the applicant must hold an MD, PhD, or equivalent 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.

At the time of application, the applicant must have attained independence from his/her mentor. Sufficient information must be included to demonstrate to reviewers and CCFA staff the high quality of the PI, the co-investigators, available research resources and the applicant institution and its support of the project. When possible, include letters of commitment for resources, such as particular pieces of equipment or lab space or letters from collaborators stating their willingness to participate in the research.

Publications – Corresponding authorship for publications in the investigator's main area of research interest.

Eligibility is not restricted by citizenship or geography.

## PROPOSAL ELIGIBILITY\RESTRICTIONS

- The submitted research proposal must be in the field of inflammatory bowel disease.
- Only one proposal may be submitted for this award per submission date.
- Applicants for a Senior Research Award may not simultaneously apply for a Training Award (Career Development or Research Fellowship Award).
- Successful applicants may not hold concurrent CCFA awards; however, applications for new projects may be submitted 6 months prior to the termination of awardees current grant.

# COMPLETING THE APPLICATION

## Deadline and Submission Requirements

CCFA uses Proposal Central system, by Altum, for all of its application submissions.
https://proposalcentral.altum.com/default.asp?GMID=96

Each applicant needs to submit a letter of intent (LOI) prior to sending a full application. The letter of intent (LOI) allows CCFA to estimate the potential application review workload and to avoid conflict of interest at the review study session. **The letter of intent is mandatory for all new applications. Resubmissions do not require a letter of intent.** The electronic LOI must be submitted by close of business (5:00pm EST) on the submission deadline, November 1 or May 1. LOI links will open 1 month prior to the submission deadline.

If your LOI is approved, you will receive an e-mail with the link to submit a full application. **As of January 2015, the CCFA no longer requires master (paper) copies of the application to be mailed to the National Office.** Applications should be submitted on proposal central by the due dates indicated below.

**If you have questions regarding the electronic process, contact CCFA by phone at 646-943-7501 or via email at grants@ccfa.org.**

**Application Timetable**

| | | |
|---|---|---|
| Letter of intent to apply due | November 1* | May 1* |
| Full Online Application due | January 14* | July 1* |
| Review | mid April | mid November |
| Board of Trustees | mid April | mid November |
| Start Date | July 1 | January 1 |
| Progress Report Due | April 1 | October 1 |

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

**Grants Department Contact Information**

For any questions or concerns please contact the CCFA Grants Department:

Telephone: 646-943-7501
Email: grants@ccfa.org

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

# LETTER OF INTENT

(stage 1 of the application process)

Each applicant must submit a letter of intent prior to sending a full application. The Letter of Intent is mandatory for all new applications. Resubmitted applications do not require a letter of intent**.** Those intending to resubmit an application and bypass the LOI stage should send notification to grants@ccfa.org including the type of application that will be resubmitted, previous submission cycle and the PI's full name and email address.

The letter of intent is due on either of the following deadlines: November 1 or May 1. **Access to the electronic version will be closed by 5:00pmET on either deadline.**

**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.

**Type of Disease**
Select one of the following Options:

- Crohn's Disease
- Ulcerative Colitis

**Eligibility Quiz**
You are required to complete an eligibility quiz. These questions are included on the Title Page of the LOI submission site. Your answers will determine if you are eligible for a CCFA Senior Research Award and if you can continue with the LOI process.

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

**Organization Information**
This indicates where the PI is located and where the study will take place.

***Abstract***

**Project Title**
Fill in the project title. Do not use abbreviations unless absolutely necessary.

**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 the general scientific audience.

**Relevance of the Project to IBD**
Provide a description of how this project is explicitly related to IBD and how it will further both research and CCFA's mission.

*Note: Lay reviewers actively participate as voting members in the peer-review process. These individuals will look specifically for the relation of the study to IBD as well as the potential for applicants to continue their careers in IBD research. It is the applicant's responsibility to clearly describe these aspects in easily*

*understandable language for the lay reviewers. Failure to do so may result in a lower recommended priority score.*

**Attachments**
Please upload the following to this section

- NIH Biosketch/CV
- Reference (optional)

## FULL APPLICATION

(Stage 2 of the application process)

The full application is due on either of the following deadlines: July 1 or January 14. **Access to the electronic version will be closed by 5:00pmET on either deadline.**

Copies of the full application must be submitted via the Proposal Central system. **The CCFA is no longer accepting paper copies of the application.**

Note: No supplemental materials will be accepted after the submission deadline unless requested by staff for administrative purposes or requested by the reviewers for clarification.

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 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, whom will administer the grant.

### KEY PERSONAL

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 CCFA's scientific priorities?
- Will this research, if successful, further the CCFA's mission to find the causes and cures of IBD and/or to improve quality of life for IBD patients? If so, how will this project do so?

Also include a brief glossary of any scientific terms included in your lay summary.

**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.

**Relevance of the Project to IBD**
Provide a description of how this project is explicitly related to IBD and how it will further both research and CCFA's mission.

**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 natures of this work; therefore, do not include proprietary or confidential information.**

## BUGET PERIOD DETAIL

**Project Start Date**
On what date do 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**
How long it will take you to complete the work.

**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) is paid by your institution for fringe benefits, such as Medical Insurance, etc.

**Detailed Budget Pages for Year 1-3 *Required**
The total budget request per year may not exceed $115,830 (Direct costs - $105,300 direct; Indirect costs - $10,530).

**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 CCFA, 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, and if yes indicate date of approval and attach approval in that Attachments Section.

Copies of the IRB approval should be provided to the CCFA 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 12 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 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.
3. Background -including preliminary data (no more than 4 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.
    - 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 6 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.
5. Significance and relevance of the proposed research to Crohn's disease and/or ulcerative colitis (no more than 1 page)
    - 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.
6. Facilities Available to carry out the Proposed Studies (one or two paragraphs)
    - 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.

7. Pertinent References (no more than 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 12 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" inch 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 3 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.).
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 3 page resubmission material limit.

**Letters of Collaboration**
Attach supporting letter(s).

**Applicants' CV/NIH Biosketch *Required**
Attach the CV/NIH Biosketch for the applicant.

**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

**New Vendor Form and W9 *Required (part of Attachments section)**
Complete so that, in the event of award, the institution is eligible to receive payment from CCFA. This document should include the name of institution as listed on the W9 as well as an attached W9 for reference. This is required even if institution has received CCFA funding in the past.

**VALIDATE AND SIGNATURE PAGE**
Once the application is validated, you can submit the application. The signature page is not required by the CCFA 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, budgetary items (particularly 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. Certification of approval from the Human Studies Committee (or its equivalent) for each participating institution should also be included. 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 Crohn's & Colitis Foundation does not assume responsibility for the conduct of the activities that the grant supports or the acts of the grant recipient as both are under the direction and control of the grantee institution and subject to the institution's medical and scientific policies. Grantee institutions must safeguard the rights and welfare of individuals who participate as subjects in research activities by reviewing proposed activities through an Institutional Review Board (IRB), as specified by the 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. If the trial is designed for more than the three-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 CCFA, 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 CCFA web site.

# REVIEW PROCESS

Applications are reviewed in a 3 step process:

**1) Peer Review of Applications**

Senior Research Award applications are reviewed by the Grants Review Committee. The review committee is composed of basic and clinical IBD researchers in a variety of fields. The committee generally has between 15-20 members; 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 and secondary reviewer (and when necessary, a tertiary reviewer).

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

- Overall Impact: All research supported by CCFA 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 of the proposal to IBD.
- 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.
- 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 committee meet to discuss, and vote to either approve or disapprove. 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.

**2) 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". (Document may be found on the “Science & Professional” section at www.ccfa.org)

**3) Board of Trustees Approval**

Following the Grants Council meeting, the Chairperson of the National Scientific Advisory Committee presents the Grant Council’s recommendations for funding at the next meeting of Board of Trustees. CCFA’s Board of Trustees, with input from the National Treasurer and President regarding budgetary constraints for the fiscal year, then considers the payment of grants.

## STATEMENT OF COMMITTEE IMPARTIALITY

To insure that the peer review process undertaken by CCFA's Grants 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:

- Application submitted or sponsored by a Senior or Clinical Research Grants Review Committee member.
- The 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

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)

- 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 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 CCFA staff.
- To review the CCFA “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.

## NOTIFICATION

An award or declination 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.)

## BUDGET POLICIES AND RESTRICTIONS

### General Policies and Restrictions for Senior Research Award

1. Awards may be for three years and for as much as $105,300 per year (direct costs), plus 10% allowable indirect costs. Total award may not exceed $115,830 per year ($105,300 for direct and
   $10,530 for indirect). Awards are made payable to the institution.

2. CCFA research awards are not meant to be a major source of a principal investigator's salary.CCFA will pay a fraction of the PI's salary commensurate with the time allotted to the project.
   - The salary request for the PI should be figured as a percentage of the NIH maximum total base salary or $184,000.
   - For example: If the PI plans to devote 10% effort to the proposed project, the salary request should be calculated at 10% of $181,100 or $18,400.

3. It is the applicant's responsibility to justify the budget. Items not adequately justified will not be supported.

4. It should be noted that CCFA offers Research Fellowship Awards and Career Development Awards, which provide salary support for research trainees (e.g. fellows, PhD candidates, etc.). Therefore, salary support for students or trainees should not be requested in the Senior Research Award application.

5. Requests for major equipment purchases (over $5,000) are not generally considered. Any equipment purchased under a CCFA award is for the use of the Principal Investigator, his collaborators and/or other researchers or trainees involved in inflammatory bowel disease research (IBD). Title to equipment shall be vested in the institution with which the principal investigator is associated. In the event the CCFA authorizes the transfer of a grant to another institution, equipment necessary for continuation of the research project purchased with the grant funds may be transferred to the new institution. Title to such equipment shall be vested in the new institution.

6. Senior Research Award applicants and collaborators are required to document all current and/or pending support from other funding sources. In cases where the applicant has been awarded support, in total or in part, for the proposed project from other funding agencies, CCFA reserves the right to examine the extent of overlap by reviewing the specific aims and budget pages of the application to other agencies. In addition, the applicant must indicate how adjustments will be made in this support if a CCFA award is received.

7. Policy on allowable indirect costs for subcontracts: Indirect costs may not exceed 10% of the awardee's direct costs. If the awardee subcontracts any portion of the work to another institution, the awardee institution may request up to a maximum of 10% of the first $25,000 of the subcontract's direct costs. Subcontract holders may request no more than 10% of their proposed direct costs for indirect costs. The awardee institution is responsible for all oversight of the subcontract and must include financial accountings for the subcontract(s) in the yearly financial report required on February 1st of each year, the close of CCFA's fiscal year.

## REPORTING REQUIREMENTS

### Progress Reports

Recipients of CCFA Senior Research Award are required to submit a progress report, outlining their accomplishments on the research project during the first 10 months of the award. Second and third year funding is contingent upon the favorable evaluation of the first and second years' progress reports. Progress reports are due and must be received 10 months after the start date of the current year of the award. Reports received after this deadline will be subject to payment hold.

**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 1st will be due on April 1st.. Annual financial reports for awards beginning on July 1, will be due on October 1st. 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.

**Grant Payments**

Grant payments are paid to institutions on a quarterly basis. 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 CCFA are not considered employees of the Foundation. Institutions are responsible for issuing the appropriate IRS tax filings for all individuals receiving compensation from CCFA grants 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 CCFA. 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. CCFA will follow the payment schedule outlined in the award letter. Please refrain from sending invoices to CCFA from the institution as these will not be paid in the manner they are received.

CCFA 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.

**No-Cost Time Extension Term Limit**

A one (1) time no-cost time extension is allowable for a maximum period of 3-6 months following the original termination date of the award without additional funds from the CCFA. A formal request for a no- cost time extension including funds to be carried over into the

extension must be submitted in writing, giving valid reason(s) for this request. Request for leave will be handled on a case-by case basis.

**Publications**

Publications resulting from research activities supported by CCFA must contain the following acknowledgement: "Supported by (insert project title of the grant and reference number) from the Crohn's& Colitis Foundation of America." The Foundation's support should also be acknowledged by the grantee and by the 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 we require that an electronic copy be sent.

The foundation shall receive timely and prior notice of any publications based upon the funded research Electronic copies of all publications must be sent to the attention of the CCFA Research Department.

**Patents**

Awards are made with the understanding that CCFA will receive written notification of the filing of any letters of patent for any discovery made based on work funded by CCFA. (Please see Patent and Intellectual Property Policy below).

## CCFA 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 Crohn's & Colitis Foundation of America ("CCFA") must be reported in writing at the earliest possible time to CCFA. The grantee institution agrees to notify CCFA within a reasonable time, preferably within 30 days, of receiving an invention disclosure or other notice indicating existence of a Property and to notify CCFA immediately of the decision to apply for letters of patent or other legal protection for the Property. CCFA 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 can not 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 CCFA 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 CCFA 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 6 months after first receipt of income. Such distribution shall be guided by the principle that CCFA's proportion of the income shall be reasonably related to CCFA's proportion of support for the research leading to the Property. The grantee institution agrees to notify CCFA within a reasonable time of beginning negotiations with potential licensees and to notify CCFA 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 CCFA'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 CCFA, including without limitation whether such license is exclusive or nonexclusive.

If any Property is made with or results from the joint support of CCFA and another organization, ~~that organization, the grantee institution, and CCFA 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 CCFA and giving CCFA 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 CCFA 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, CCFA's introduction of the licensee to the grantee institution shall be counted to the benefit of CCFA 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, CCFA shall be entitled to a share of any relicensed Property income according to the principles set forth above.

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

CCFA shall have use of the Property without payment of royalties or license fees solely for the use by CCFA 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.

**Change of Institution**

Recipients of a Senior Research Award may transfer their grant from one institution to another. Requests will be reviewed by an administrative committee after full details of the new environment and budget have been provided. Contact the Research & Scientific Programs Department at the National Office to alert them of your intent to transfer.

a. Written authorization from administrative 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 CCFA 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.