

CROHN'S & COLITIS FOUNDATION OF AMERICA

Senior Research Award

POLICIES

Effective May 2011

**Crohn's & Colitis Foundation of America
National Office
Research & Scientific Programs Department
386 Park Ave South – 17th Floor
New York, NY 10016-8804**

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

**SENIOR RESEARCH AWARD
POLICIES**

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**RESEARCH GRANT FOR INDEPENDENT INVESTIGATORS
SENIOR RESEARCH AWARD
POLICIES**

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 Career Development Award may not simultaneously apply for a 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.

DEADLINES AND SUBMISSION REQUIREMENTS

IGAM (Internet Grant Application Module) is hosted on a web browser on the Crohn's and Colitis Foundation of America (CCFA) web site. Access is available using links provided at ccfa.org.

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.** 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 an LOI is approved, applicants will receive an e-mail with the link to submit a full application. The electronic full application must be submitted by close of business (5:00pm EST) on the submission deadline July 1 or January 14. The master (paper copy) of full application with original signatures must be postmarked on or before the submission deadline July 1 or January 14. Please mail full (master) application to:

Crohn's & Colitis Foundation of America
Research and Scientific Programs Department
386 Park Avenue South – 17th Floor
New York, NY 10016-8804

Once submitted, you will receive an e-mail confirmation. If you have not received this within 48 hours of submission, please contact the help desk. If it is determined that some part of the application was lost or did not transfer correctly during the submission process, CCFA has the option to "Reject" the application. If you are unsure, please contact the help desk to ensure that the issues are addressed and corrected.

If you have questions regarding the electronic process, go to our website for our [online tutorial](#) or contact the 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*
Submission of Paper Copy	Postmarked January 14*	Postmarked 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.

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:

- **Relevance to IBD:** 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.
- **Scientific Merit:** 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 5.0 the lowest.

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.

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 application submitted or sponsored by a Grants Review Committee member during the cycle. This also applies to all committee chairpersons.
2. Committee members are excused from the review room during the discussion of proposals from their own institutions or from collaborating institutions, and do not rank those applications. Applications and reviews of an applicant's proposal are not available to committee members who have such conflicts of interest.
3. Reviews and applications are treated with utmost confidentiality and are not circulated to anyone outside the review committee membership.

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.)

TERMS OF THE AWARD

Duration

Awards are granted for one to three years. The foundation retains the right to renew each year only if a satisfactory progress report is received.

Amount

CCFA research award is not to be a major source for the PI's salary.

The total direct cost of the award can be as much as \$117,000 per year. Indirect costs may be as much as \$11,700 per year, i.e. 10% of the total award. The maximum total award amount given per year is therefore \$128,700.

BUDGET POLICIES AND RESTRICTIONS

General Policies and Restrictions for Senior Research Award

1. Awards may be for three years and for as much as \$117,000 per year (direct costs), plus 10% allowable indirect costs. Total award may not exceed \$128,700 per year (\$117,000 for direct and \$11,700 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.
 - o The salary request for the PI should be figured as a percentage of the NIH maximum total base salary or \$199,700.
 - o For example: If the PI plans to devote 10% effort to the proposed project, the salary request should be calculated at 10% of \$199,700 or \$19,970.

3. It is the applicant's responsibility to justify the budget. Items not adequately justified will be deleted.
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.
8. Expenditures: It is the intent of the Foundation to be flexible in response to the changing needs of a research project. The principal investigator may make minor adjustments to the approved budget except where such expenditures conflict with the policies of the foundation. Major changes require written approval from the foundation.

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 nine 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 nine months after the start date of the current year of the award. Reports received after this deadline may be rejected and may result in termination of the award.

Final Scientific Report

The final scientific report, a brief summary of progress toward the achievement of originally stated aims, is due 30 days after the end of the project.

Financial Reports

Financial reports are due February 1st, and at the end of the project. The February 1 report 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 note: the final payment will be held until the final financial report is received and approved.

Any unexpended funds must be returned to the Foundation upon termination of the project.

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.

Grant Payments

Grant payments are paid to institutions on a monthly basis at the beginning of each month (e.g. funds covering the January 1 – January 31 month will be forthcoming on or about January 10th). Payments may be made via check or by electronic transfer. Acknowledgement of payment by the grantee institution is not required.

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 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.

Final Payment

Final payments are made only upon receipt of both final scientific and financial reports.

Note: Grantees who do not fulfill all obligations of the CCFA award are prohibited from applying for additional CCFA awards.

Any unexpended funds must be returned to the Foundation upon termination of the project.

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 support, in whole or in part, of research, training grants or 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. Each grantee institution further agrees to seriously consider, in good faith, any comments, suggestions or objections that CCFA may have concerning such applications or other legal protection. 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 unreasonable 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 and provide a copy of the license or other agreement to CCFA.

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 reasonable opportunity to take title to the Property.

The grantee institution agrees that when it licenses a Property, it will obligate the licensees as follows: The licensee shall agree 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. In the event the licensee has failed to commercialize the

Property within the number of years determined to be reasonable for that Property, and minimally a three-year period, the grantee institution, upon conferring with CCFA, shall have the right to convert an exclusive license to a non-exclusive license or terminate an existing non-exclusive license with such licensee. If the licensee or grantee institution has an ongoing and active research, development, manufacturing, marketing or licensing program as appropriately directed toward the production and sale of the Property, the same would be deemed to be sufficient evidence that the licensee or grantee institution has commercialized the Property.

The grantee institution acknowledges complete responsibility for all aspects of the research, investigation, funding and administration of and in connection with the grant award. To the extent permitted under the international, federal, state and local laws which govern the grantee institution, the grantee institution shall indemnify and hold CCFA harmless from and against any and all costs, losses or expenses, including reasonable attorneys' fees, that CCFA may incur by reason of the grantee institution's negligence or misconduct or any third-party claim arising out of or in connection with the project which is the subject of the grant.

Grantee institution shall be required to maintain adequate liability insurance comparable to coverage held by institutions of similar size and nature, covering the employees, officers and agents of CCFA for the duration of the project. CCFA may request to be provided certificates evidencing the insurance coverage at any time during the term of the project.

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. Cover (face) and second page of application completed and signed by the appropriate individuals at the new institution.
- d. Full details of the new environment and budget
- e. New personnel – names, time spent on the award
- f. Description of any changes to the original protocol
- g. IRB certificate/research consent forms if applicable
- h. 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.