

CROHN'S & COLITIS FOUNDATION OF AMERICA

Career Development 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**

**Voice: 800-932-2423 Ext. 7501
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.

Crohn's & Colitis Foundation of America

CAREER DEVELOPMENT AWARD

POLICIES

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RESEARCH GRANT FOR MENTORED INVESTIGATORS BASIC AND CLINICAL CAREER DEVELOPMENT 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 identifies the most meritorious and innovative projects for funding.

OBJECTIVE

The foundation's Research Training Awards Programs offers Career Development Awards to encourage the development of individuals with research potential to help them prepare for a career of independent basic and/or clinical investigation in the area of Crohn's disease and ulcerative colitis research.

Applicants should note that these awards are for the purposes of encouraging research into the inflammatory bowel diseases and developing the potential of young, outstanding basic and/or clinical scientists. Therefore, individuals who are already well established in the field of IBD research are not considered eligible for this award.

APPLICANT ELIGIBILITY

At time of application, the applicant must:

1. Hold an M.D., Ph.D., or equivalent degree.
2. Be employed by an institution (public non-profit, private non-profit, or government) engaged in health care and/or health related research within the United States. Research is not restricted by citizenship. However, proof of legal work status is required.
3. Candidates holding M.D. degrees must have at least five years of post-doctoral experience, two years of which must be documented research experience relevant to IBD prior to application. Candidates holding Ph.D. degrees must have at least two year of documented post-doctoral research relevant to IBD prior to application.

PROPOSAL ELIGIBILITY

- 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.

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.

CCFA includes lay reviewers as part of its evaluation process. These individuals look specifically for the relation of the study to IBD as well as the potential for applicants to continue their careers in IBD research.

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

(Faxed or e-mailed submissions will not be accepted).

Once submitted, applicants receive an e-mail confirmation. If this has 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. 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.

For questions regarding the electronic process, visit our website for our [online tutorial](#), or contact the CCFA by phone at 646-943-7501 or email at grant@ccfa.org.

APPLICATION TIME TABLE

Letter of intent to apply due	November 1*	May 1*
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 3 step process:

1) Peer Review of Applications

The Research Training Awards Committee is composed of basic and clinical IBD researchers in a variety of fields. 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:

- Intellectual background of the applicant
- Applicant's research experience
- Mentor's track record
- Number of important techniques to be learned
- Importance of the research area
- Relevance to IBD
- Applicant's career objectives

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. At the Peer Review Committee Meeting, the applications are discussed, and votes are held 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. Although each award is made for up to three years, the foundation retains the right to renew each year only if a satisfactory progress report is received. (See Budget Policy and Restrictions for further information).

Time Commitment

The awardee must devote a minimum of 80% of his/her time directly to the project.

Amount

Basic Research – total award not to exceed \$90,000 per year for up to three years:

1. CCFA will match the applicant's institutional salary (salaries may be supplemented by the applicant institution), depending on postgraduate year (PGY) level, up to \$52,000 per year.
2. CCFA allows for fringe benefits according to institutional policy, not to exceed 25% of the salary award (up to \$13,000 per year).
3. CCFA will provide up to \$25,000 to be used for non-salary/fringe expenses directly related to the project, including supplies, technical support, tuition, travel or professional memberships. These funds may not be used to supplement the awardee's salary/fringe benefits. *Note: a portion of this money must be used to attend the CCFA Advances Conference which is held every December.*

Clinical Research – total award not to exceed \$90,000 per year for up to three years:

1. CCFA will match the applicant's institutional salary (salaries may be supplemented by the applicant institution), depending on postgraduate year (PGY) level, up to \$52,000 per year.
2. CCFA will also allow for fringe benefits according to institutional policy, not to exceed 25% of the salary award (up to \$13,000 per year).
3. CCFA will provide up to \$25,000 to be used for non-salary/fringe expenses such as:
 - a. Master of Public Health Degree (MPH), or equivalent tuition: it is required of all clinical research applicants to complete this degree within the three-year window of this award.
 - b. Statistical support, travel to professional meetings, professional memberships, and textbooks. These funds may not be used to supplement the awardee's salary/fringe benefits.

Note: a portion of this money must be used to attend the CCFA Advances Conference which is held every December.

Mentorship

All applicants 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 term of the Career Development Award. The applicant may have an additional mentor(s) either within or outside the sponsoring institution.

All mentor(s) will be responsible for submitting a progress report on the applicant and his/her research, to be attached to the applicant's Progress Report.

BUDGET POLICIES AND RESTRICTIONS

General Policies and Restrictions for Career Development Award

1. It is the applicant's responsibility to justify the budget. Items not adequately justified will be deleted.
2. No indirect costs are allowed.
3. 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/her collaborators and/or other researchers or trainees involved in inflammatory bowel disease research. Title to equipment shall be vested in the institution with which the principal investigator is associated. In the event that 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.
4. Expenditures: It is the intent of the Foundation to be flexible in response to the changing needs of a research program. 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.
5. In cases where the researcher has been awarded support, in total or in part, from other funding agencies, CCFA reserves the right to revoke its award.
6. Institutions may not reallocate funds of budget without the expressed written permission by the Foundation.

REPORTING REQUIREMENTS

Progress Report

Recipients of CCFA Career Development 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 authorized 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.** All mentor(s) will be responsible for submitting a progress report on the applicant and his/her research, to be attached to the applicant's Progress Report.

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.

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 Career Development 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. Completed *Request for Change of Institution form* (available upon request)
- b. Written authorization from administrative official at the new institution accepting the award
- c. Letter of release from present institution relinquishing the award
- d. Letter from new mentor(s)
- e. Mentor's CV (if new)
- f. Signature pages completed and signed by the appropriate individuals at the new institution
- g. Full address for PI and new institution

- h. Full details of the new environment and budget
- i. Description of any changes to the original protocol
- j. IRB certificate/research consent forms if applicable
- k. A financial accounting from the present institution within 30 days of the award

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 have been approved by the foundation.

Recipients of NIH K-Level Awards

Recipients of CCFA Career Development Awards who received NIH K-level awards prior to the completion of the CCFA award are eligible to retain the supply budget portion of the Career Development Award for the normal duration.

To request retaining the supply budget of the CCFA Career Development Award, applicants must submit a formal letter to include the following information:

- Letter of notification of NIH award
- Type of NIH award
- Project Title
- Overall Budget
- Specific Aims
- Outline of how the original CCFA sponsored work fits into the new NIH project
- Description of how the CCFA funds will be used in the new project

Withdrawal 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 the 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.