CROHN'S & COLITIS FOUNDATION OF AMERICA

Career Development Award

POLICIES

Effective January 2016

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

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.
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 years 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.
Deadline and Submission Requirements

CCFA grant applications are conducted through Proposal Central. Please use the site below to access available grant opportunities and submission instructions.

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.** 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. 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 to be mailed to the National Office.** Applications should be submitted on proposal central by the due dates indicated below.

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, contact CCFA by phone at 646-943-7501 or via email at grants@ccfa.org.**

**Application Timetable**

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<tr>
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<th>November 1*</th>
<th>May 1*</th>
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<tr>
<td>Letter of intent to apply due</td>
<td></td>
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<tr>
<td>Full Online Application due</td>
<td>January 14*</td>
<td>July 1*</td>
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<tr>
<td>Review</td>
<td>mid April</td>
<td>mid November</td>
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<tr>
<td>Board of Trustees</td>
<td>mid April</td>
<td>mid November</td>
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<tr>
<td>Start Date</td>
<td>July 1</td>
<td>January 1</td>
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<tr>
<td>Progress Report Due</td>
<td>April 1</td>
<td>October 1</td>
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*Should the deadline date fall on a weekend or national holiday, the submission deadline will be extended to the following business day.

**Help Desk Information**
For any questions or concerns please contact the CCFA Research helpdesk:

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

Applications are reviewed in a 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 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 9.0 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 via email 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 within the following months after a funding decision has been made. 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

* Please note all financial and scientific reports MUST be uploaded to Proposal Central. Emailing documents to the grants department will not suffice.

**Progress Report**
Recipients of CCFA Career Development Award are required to submit a progress report via proposal central, outlining their accomplishments on the research project during the first ten 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 ten 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 on proposal central 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 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 quarterly basis at the beginning of each quarter (January, April, July, October). Payments may be made via check unless special arrangements have been made otherwise. 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 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.

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.

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Change of Institution

Recipients of a Research Fellowship Award may transfer their grant from one institution to another. Projects that have been funded for six months or longer will be reviewed by an administrative committee after full details of the new environment and budget have been provided. Contact the Research & Scientific Programs Department at the National Office to alert them of your intent to transfer. For a complete list of what documentation is required, please contact the Research and Scientific Programs Department at the National Office using the email address or phone number provided on the first page.

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.
Withdrawal of Application
Please advise the Foundation promptly, via email, 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 via email of any changes of address, email or phone number, following the submission of an application.