CROHN'S & COLITIS FOUNDATION OF AMERICA

Career Development 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.

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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.

Deadline and Submission Requirements

CCFA grant applications are conducted through ProposalCentral. 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 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. A hard copy of the LOI is not required.

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.

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 Research helpdesk:

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.**

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

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 Career Development 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 is the location of where the PI is located and where the study will take place.

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.

Mentor Information
Please use this area to fill out the information for the researcher that will be mentoring you on this study. Only one mentor can be included in the Letter of Intent stage. Additional mentors may be named as part of the full application.

Attachments
Please upload the following to this section

- NIH Biosketch/CV
- References (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.

Below you will find detailed instructions on completing these various sections.

Some of the required information will have been automatically filled in from your Letter of Intent submission.

General Information:

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.

Lloyd Mayer Award
Please select your interest in receiving a Lloyd Mayer Award. This award is in honor of Lloyd Mayer, MD (1952 - 2013), a visionary leader and brilliant scientist whose life was dedicated to finding cures for patients with IBD and improving the quality of life of those suffering from these diseases. For almost 30 years, Dr. Mayer was the driving force behind CCFA's research programs, leading and innovating new ideas to move the field forward. He was especially passionate about bringing young investigators into the IBD field and support their career development.

Dr. Mayer's own laboratory focused on mucosal immunoregulation in inflammatory bowel diseases: cytokine regulation of human B-cell differentiation with special attention to the role of intestinal epithelial cells (IEC) in regulatory T-cell responses in the gut. He and his team were the first to show that epithelial lining of the intestine was an active regulator of mucosal immune responses and that this regulation was distinct from systemic immunity. These findings had a significant effect on the development of highly-effective anti-inflammatory drugs for IBD.
Dr. Mayer was a dedicated and awe-inspiring teacher, mentor, and colleague to many IBD researchers worldwide and a staunch friend to CCFA. His passion, leadership, scientific expertise, and commitment to improving the lives of our patients will be a legacy at CCFA.

The ideal candidate for this award will be an exceptional early career scientist who emulates Dr. Mayer's passion for innovative research in studying IBD immunology and mucosal health, as well as his commitment to fostering a robust IBD research community through leadership and collaboration.

APPLICANT/ PI

Principal Investigator
PI is defined as the one person responsible to the foundation for scientific and technical direction of the project. Only one (1) Principal Investigator will be accepted on a proposal; co-investigator designations are not allowed.

Organization Information
This is the location of where the PI is located and where the study will take place.

INSTITUTION AND CONTACTS

Mentor Information
In this area please fill out the information for the researcher that will be mentoring you on this study. All applications must have at least one mentor at the sponsoring institution who agrees to be available to provide advice and guidance to the awardee during the entire Career Development Award.

Grant Administrator 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.

Applications that are not funded may be revised and resubmitted no more than 2 times. All resubmissions are competitively reviewed. Any resubmission of a previously submitted proposal should carry the same title as the previous application.

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
Date on which 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
Length of time you expect to devote to this project in order to complete the work.

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. This number cannot be higher than 25%.

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. This breakdown includes your research duties, clinical duties, teaching duties and any other tasks that are required by you by your employment at the institution. Career Development Award recipients are required to dedicate at least 80% of their time to the CCFA project.

Example:
Laboratory Research- 30%
Clinical Responsibilities- 40%
Teaching- 10%

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 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.

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 10 pages, single spaced. Applications exceeding the page limit may not be reviewed.*

1. Statement of purpose and specific aims.
    - Concisely state the specific aims of the study, goals, deliverables and timelines
2. Background studies for proposed project (including preliminary data).
    - Provide a brief statement of the ideas and reasoning behind the proposed work
3. Experimental design.
    - Briefly describe the study design, emphasizing those elements you consider most relevant to assignment of the proposal for peer review
4. Detailed description of methods and materials to be used.
    - Describe your proposed methods and procedures in sufficient detail to permit evaluation by other scientists.
    - Discuss potential difficulties and limitations of the methods and procedures, and provide alternative approaches.
    - Prioritize, and estimate the length of time that you believe will be required to complete each specific aim. Although the time estimated should not exceed the term for which support is requested, it is helpful to state how this project fits in with your long term research goals.
5. Significance and relevance of the proposed research to Crohn's disease and/or ulcerative colitis.
    - Provide a brief statement explaining the potential relevance to IBD of the proposed work
6. Pertinent References (no more than 3 page)
    - Literature citations should be listed in this section, at the end of the Research Plan. ***These are not counted as part of the 10 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.

Mentors' Letter of Support *Required (part of Attachments section)
Attach supporting letter from your mentor(s). This should include the following information:

- Description of the facilities and equipment available for the proposed project
- Outline of training program (i.e.: courses, workshops, etc) for the applicant

Institutional Letter of Support *Required (part of Attachments section)

A letter from the applicant's Department Chairperson, or authorized institutional representative, guaranteeing protected research time commensurate with the percentage of effort/salary to be devoted to the research project.

NIH Biosketch (Mentor) *Required
Attach the NIH Biosketch for all Mentor(s).

Applicants' CV/NIH Biosketch *Required (part of Attachments section)
Attach the CV/NIH Biosketch for the applicant. The Applicant Biosketch must also contain:

- Discussion of short and long-term career plans in IBD (1-2 pages)

Applicants' Research Experience *Required (part of Attachments section)

- Research Experience (template available in Downloads section)

Proof of Work Status- Optional
Non-U.S. Citizens must upload documentation which shows their proof of status to work in the United States. This may include a copy of their green card, or work visa.

Additional Mentor Page- Optional
Upload information on additional mentor(s), whom are not already listed on the main application.

Letter(s) of Collaboration - Optional (part of Attachments section)

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

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.

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.

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 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 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 as well as policies and methods concerning blinding of study results. Accordingly, a plan should be submitted describing the procedure for the coordination of all participating centers. CCFA 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 (DHHS). Furthermore, grantee institutions must adhere to DHHS guidelines regarding financial conflicts of interest, recombinant DNA, research misconduct and vertebrate animals. 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:
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. A copy of the actual signed or stamped approval is required. Enclose letters of commitment from each participating center, signed by the cooperating investigator and business official. In addition, informed consent forms 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 (2 PAGES EACH ONLY).

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 post-CCFA 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 part 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 on the attachment section provided. The forms can be found in the form section of the CCFA web site.

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 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 and commitment 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. 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.

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 (≥ 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

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.

REPORTING REQUIREMENTS

Progress Reports

Recipients of CCFA Career Development 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 an annual basis. 80% of year 1 will be paid at the beginning of the award when all assurances and terms of the award have been submitted. Year 2 funding will include the remainder of year 1 as well as 80% of Year 2 and will be sent at the start of year 2. Year 3 Funding (if applicable) will include the remainder of year 2 as well as 80% of Year 3. The final payment of the remaining balance will be sent once all final reports have been received and approved. 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.

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.

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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.