

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

**Career Development Award**

**INSTRUCTIONS**

**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](mailto: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.

**CDA INSTRUCTIONS  
TABLE OF CONTENTS**

<b>GENERAL INFORMATION .....</b>	<b>4</b>
Deadline and Submission Requirements .....	4
Application Timetable .....	4
Formatting the Application .....	4
File Size .....	5
Uploading Documents- Naming Format .....	5
Assembly and Submission of Paper Copy .....	5
Help Desk Information .....	5
<b>LETTER OF INTENT .....</b>	<b>2</b>
Eligibility Quiz .....	2
Principal Investigator .....	2
Organization Information .....	2
Type of Support .....	3
Type of Disease .....	3
Project Title .....	3
Scientific Summary of Project .....	3
Relevance of the Project to IBD .....	3
Mentor Information .....	3
Attachments .....	3
<b>FULL APPLICATION .....</b>	<b>4</b>
Type of Disease .....	4
General Area of Research .....	4
Challenges Priority .....	4
Project Title .....	4
Principal Investigator .....	4
Organization Information .....	5
Mentor Information .....	5
Grant Administration Information .....	5
Resubmissions .....	5
Type of Support .....	6
Scientific Summary of Project .....	6
Lay Summary .....	6
Approximate Project Start Date .....	7
Estimated Length of Project .....	7
Percentage of Fringe Benefits Paid by Your Institution .....	7
Percentage Estimation of Amount of Time Allocated to this Project .....	7
Current Financial Support .....	7
Pending Application .....	7
Projected Institutional Salary for (PGY) .....	7
Institutional Support .....	8
Human/Animal Studies Approval .....	8
Research Plan/Protocol* Required .....	8
Detailed Budget Pages for Year 1-3 *Required .....	9
Justification of Personnel Budget *Required .....	9
Letters of Support (Mentor) *Required .....	10
NIH Biosketch (Mentors) *Required .....	10
Signature Page *Required .....	10
Applicants Research Experience *Required .....	10

Applicants CV/NIH Biosketch *Required .....	10
Proof of Work Status- Optional.....	10
Additional Mentors Page- Optional.....	10
Resubmission Material *Required if this is A Resubmission .....	10
References/ Appendices- Optional.....	11
Human and/or Animal Approvals- Optional .....	11
Abstract for Pending Applications- Optional .....	11
Electronic Transfer- Optional:.....	11
<b>SPECIAL INSTRUCTIONS FOR CLINICAL TRIALS.....</b>	<b>12</b>

## GENERAL INFORMATION

### Deadline 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](http://ccfa.org).

Each applicant needs to submit a letter of intent (LOI) prior to sending a full application. The letter of intent (LOI) allows CCFA to estimate the potential application review workload and to avoid conflict of interest at the review study session. **The letter of intent is mandatory.** The electronic LOI must be submitted by close of business (5:00pm EST) on the submission deadline, November 1 or May 1. LOI links will open 1 month prior to the submission deadline.

If your LOI is approved, you will receive an e-mail with the link to submit a full application. The master (paper copy) of full application with **original signatures** must be sent to CCFA and be postmarked on or before the submission deadline of July 1 or January 14. See further instructions "Assembly and Submission of Paper Copy" on Page 4.

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

**If you have questions regarding the electronic process, go to our website for our [online tutorial](#) or contact the CCFA at 646-943-7501 or email us at [grants@ccfa.org](mailto:grants@ccfa.org).**

### Application Timetable

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

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

### Formatting the Application

Applicants must adhere to the following instructions in completing the proposal sections that compose the electronic version of the application. Failure to observe font size specifications and/or page limits will result in rejection of the application without review:

- Please insert your name in the header on each form in the attachment section.
- Font size: Use 11-point Arial as the minimum font size for the text of the application. A 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 .5" inch all around, unless a form with different margins is supplied in the Application Templates or Forms.
- Fill in all required fields (\*)

## File Size

**Important! File Size Limit:** Most foundations limit the size of the files they will accept. The purpose for limiting file size, as well as page limits, is to facilitate review of the application. Very large files can make a full and comprehensive review of the application extremely difficult as many of our review panel members must download your PDF uploads. Therefore, **uploaded PDF files can be no larger than 25 MB.** The objective is to find a balance between the content of your application and file size.

## Uploading Documents- Naming Format

The paper copy (master) of the full application must be postmarked no later than the deadline date (July 1 or January 14) to the Crohn's & Colitis Foundation National Office. The paper (master) copy of the full application must contain assembled in this order:

- Last name, First name – Research Plan or Protocol
- Last name, First name – Detailed Budget Pages for Year 1 -3
- Last name, First name – Letters of Support (*Indicate Name of Mentor*)
- Last name, First name - Mentor's NIH Biosketch (*indicate name of Mentor*)
- Last name, First name – Signature page
- Last name, First name – Applicant's Research Experience
- Last name, First name - Applicant's CV/NIH Biosketch
- Last name, First name – Proof of Work Status
- Last name, First name – Additional Mentor Page
- Last name, First name - Resubmission Materials
- Last name, First name – References/ Appendices
- Last name, First name – Human & Animal Approvals
- Last name, First name – Abstract for Pending Application(s)
- Last name, First name – Electronic Transfer

**All attachments must be uploaded as .pdf documents.**

## Assembly and Submission of Paper Copy

The paper copy (master) of the full application must be postmarked no later than the deadline date (July 1 or January 14) to the Crohn's & Colitis Foundation National Office. The paper (master) copy of the full application must contain assembled in this order:

- Application Forms
- Budget Pages
- Justification of Personnel Budget
- Research Plan (Protocol)
- Mentor Letters and/or Letters of Collaboration
- NIH Biosketch for PI and Mentors
- Applicant Research Experience
- Human & Animal Approval (optional)
- Resubmission
- Signature page (**original signatures**)
- Appendices (optional)

Mail to:

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

Note: Faxed or e-mailed submissions will not be accepted. No supplemental materials will be accepted after the submission deadline unless requested by staff for administrative purposes or requested by the reviewers for clarification.

## Help Desk Information

For any questions or concerns please contact the CCFA Research helpdesk:

Telephone: 646-943-7501

Email: grants@ccfa.org

**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.

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.**

Resubmitted applications do not require a letter of intent.

**Eligibility Quiz**

You are required to complete an eligibility quiz. Your answers will determine if you are eligible for a CCFA Research Fellowship Award and if you can continue with the LOI process.

FILL IN TEXT BOXES FOR ALL OF THE FOLLOWING:

- Select degree that best match your credentials
- Employed by health organization within the U.S.
- Type of organization
- Independent of a mentor
- If MD applicant, 2 years post-doctoral experience in IBD
- If PhD applicant, 1 year post-doctoral experience in IBD

**Contact Information**

**Principal Investigator**

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

FILL IN TEXT BOXES FOR ALL OF THE FOLLOWING:

- Name: FIRST name, MIDDLE name, LAST name
- Degree:(e.g. M.D., Ph.D.)
- Academic Title
- Address: Complete mailing address for correspondence to the applicant
- City, State, Postal Code
- Telephone: The phone number at which you are most likely to be reached during the day.
- Fax and E-mail

**Organization Information**

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

FILL IN TEXT BOXES FOR ALL OF THE FOLLOWING:

- Organization Name
- Address
- City, State, Postal Code
- Phone and Fax
- Tax ID
- Website (www) URL

## **Abstract**

### **Type of Support**

Select one of the following Options:

- Career Development Award Basic
- Career Development Award Clinical

### **Type of Disease**

Select one of the following Options:

- Crohn's Disease
- Ulcerative Colitis

### **Project Title**

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

### **Scientific Summary of Project**

The Scientific Summary should provide a clear, concise overview of the proposed work, including the background, objective, or hypothesis and its supporting rationale; specific aims of the study for the general scientific audience. This should be no more than one-half page.

### **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. This should be no more than one-half page.

*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.*

### **Mentor Information**

Please use this area to fill out the information for the researcher that will be mentoring you on this study. Please note that you can enter up to two mentors using this system. If you have more than two, download the Additional Mentor document and complete this with the additional mentor names.

FILL IN TEXT BOXES FOR ALL OF THE FOLLOWING:

- Name: FIRST name, MIDDLE name, LAST name
- Degree: (e.g. M.D., Ph.D.)
- Academic Title
- Mentor Institution
- Address
- City, State, Postal Code
- Phone and Fax
- E-mail

### **Attachments**

Please upload the following to this section

The Principal Investigator's name should be in the upper right-hand corner of each uploaded .pdf page

- NIH Biosketch/CV
- Reference (optional)
- Mentor Contact Information (for Additional Mentor(s))

**\*\*NOTE: Paper copy of your Letter of Intent is not required.**

**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.**

Complete the electronic version of your application as follows:

Below you will find detailed instructions on completing these various sections. You will also find instructions on compiling the paper copy of your application for submission. **All application attachments must be uploaded as .pdf documents.**

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

***General Information***

**Type of Disease**

Select one of the following Options:

- Crohn's Disease
- Ulcerative Colitis

**General Area of Research**

Indicate the scientific area(s) of your project.  
Select 3 categories from the drop down box

**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.

**Project Title**

Fill in project title (If this is a resubmission, the title should be the same as the original application.)

***Applicant Information***

**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.

FILL IN TEXT BOXES FOR ALL OF THE FOLLOWING:

- Name: FIRST name, MIDDLE name, LAST name
- Degree:(e.g. M.D., Ph.D.)
- Academic Title
- Gender
- Ethnicity
- Nationality: If none- US Citizen, Fill in information regarding Visa Work Status
- Institution Name
- Address: Complete mailing address for correspondence to the applicant
- City, State, Postal Code
- Telephone: The phone number at which you are most likely to be reached during the day.
- Fax and E-mail

### **Organization Information**

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

FILL IN TEXT BOXES FOR ALL OF THE FOLLOWING:

- Organization Name
- Address
- City, State, Postal Code
- Tax ID
- Website (www) URL

### **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 Award.

Please note that you can enter up to two mentors using this system. If you have more than two, download the Additional Mentor document and complete this with the additional mentor names.

FILL IN TEXT BOXES FOR ALL OF THE FOLLOWING:

- Name: FIRST name, MIDDLE name, LAST name
- Degree:(e.g. M.D., Ph.D.)
- Organization Name
- Business Address
- City, State, Postal Code
- Phone and Fax
- E-mail

### **Grant Administration Information**

In the event an award is made, provide the name and address of the person, at the grantee institution, whom will administer the grant.

FILL IN TEXT BOXES FOR ALL OF THE FOLLOWING:

- Name: FIRST name, LAST name
- Organization Name
- Address
- City, State, Postal Code
- Telephone
- Fax
- E-mail

### ***Abstract***

### **Resubmissions**

**(Leave this section blank if application is new)**

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.

PROVIDE THE FOLLOWING INFORMATION:

- Number of times grant has been submitted  
Cannot be resubmitted more than 2 times
- Previous Submission date (Leave this section blank if application is new)  
Enter here month, day and year of previous submission
- Previous Submission Score (Leave this section blank if application is new)  
Enter score received for previous submission

## **General Information Regarding the Study**

### **Type of Support**

Select one of the following Options:

- Career Development Award Basic
- Career Development Award Clinical

### **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. This should be no more than one-half page.

### **Lay Summary**

CCFA has instituted a Stakeholder Reviewer Program, in which selected lay people participate as full voting members of the various review committees. 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. **Failure to provide a clear and well thought out lay description may result in a non-fundable score.** The lay summary should be no more than 1-2 pages and 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.

**This statement 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.**

Pointers:

- This section must be written in language that is easily understandable to a 6th-7th grade reader.
- Define all scientific terms; Words like "pathogenesis" or "cytokines" might be common words to you, but not necessarily to lay persons.

### Template for Writing the Lay Summary

**Investigator:** Burrill Bernard Crohn, MD  
Mount Sinai Hospital

**Project:** Gender differences in growth in pediatric patients with Crohn's disease

**Type of Award:** Career Development Award

**Description:** Growth failure is a unique and important problem for children with IBD. The exact causes of growth failure, and how best to treat them, is a pressing need. In children with Crohn's disease, boys and girls differ in disease severity and growth failure. That is, female patients tend to have more severe clinical disease but don't suffer from growth failure, while male patients tend to have less severe clinical disease and suffer from growth failure. Understanding the reasons for these differences could provide new clues on the reasons for disease severity and growth

affects of IBD, and how better to treat them. This project tests whether sex hormones (estrogen in females, testosterone in males) act differently on the function of hormones controlling growth (growth hormone itself, Insulin-like Growth Factor-1 [IGF-1], and the pathway linking them). This project will study 90 pediatric Crohn's patients under the age of 17, matched to a control group of patients with short stature alone (unrelated to Crohn's disease), and determine whether disease activity affects growth hormone/IGF-1 levels, and how this affects growth in kids with Crohn's.

**Significance:** If successful, this project will establish whether a combination of sex and growth hormone levels can be used to predict growth failure. This information could help identify children with different biologic types of growth failure, and guide the development of more targeted treatments to correct them.

**Relevance of the Project to IBD:** Use our [Challenges Comparison Worksheet](http://www.cafa.org/ccfaprof/research-grant-ops/) on our website at <http://www.cafa.org/ccfaprof/research-grant-ops/> to find out which CCFA scientific priority listed is addressed by your project (choose one only).

### **Approximate Project Start Date**

On what date do you expect to start this project

### **Estimated Length of Project**

How long will it take you to complete the work (in months)

### **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. Fill in % in the text box. 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.

Example:

Laboratory Research- 30%

Clinical Responsibilities- 40%

Teaching- 20%

### **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 Application**

If you do not have any current pending applications please type in "No".

If you do have current pending applications, type in the title of the award(s) and the name of the agency from which you are awaiting a response. In the attachment section, attach an abstract for each application you list in this section.

### **Projected Institutional Salary for (PGY)**

Type projected amount(s) (\$.....)

## **Institutional Support**

Fill in how much institutional support you currently have. If none, type in none.

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.

## **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 to the CCFA National Office should be sent by mail to the address listed above. If approval is not available at the time of application, provide a date of anticipated approval. **This approval must be received before the start date of the approved grant.**

## **Attachments**

Please upload the following to this section

\* Indicates Required

## **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 should not exceed 10 pages, single spaced.

1. Statement of purpose and specific aims (no more than 1 page)
  - Concisely state the specific aims of the study, goals, deliverables and timelines
2. Background -including preliminary data (no more than 3 pages)
  - Provide a brief statement of the ideas and reasoning behind the proposed work
3. Experimental design (no more than 2 pages)
  - 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 (no more than 3 pages)
  - 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 (no more than 1 page)
  - Provide a brief statement explaining the potential relevance to IBD of the proposed work

6. Pertinent References (no more than 3 page)

- o 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.

Research Plan Section	Page Limit
Statement of purpose and specific aims	1 Page
Background -including preliminary data	3 Pages
Experimental design	2 Pages
Detailed description of methods and materials to be used	3 Page
Significance and relevance of the proposed research to Crohn's disease and/or ulcerative colitis	1 Page
Pertinent References	3 Pages (not part of Research Plan)

**Detailed Budget Pages for Year 1-3 \*Required**

The Budget and Justification of Personnel Budget Forms may be downloaded from the web site [Career Development Section](#) of the CCFA website. Complete budget page(s) for all years requested then fill in the total budget for year one for PI and technical personnel. The total budget request per year may not exceed \$90,000 (Salary -\$52,000; Fringe Benefit -\$13,000 and Supplies, etc. -\$25,000).

**Fill in on the e-form total budget for first year.**

FILL IN TEXT BOXES FOR ALL OF THE FOLLOWING:

- PI Percent of effort: How much effort the PI will dedicate to this project (Min. 80%)
- PI Salary: Enter PI salary for year 1. Calculate the salary based on your (PGY), e.g. if your PGY exceeds \$52,000 then use \$52K to calculate your salary. If it is below \$52K then use the lower number.
- PI Fringe Benefit Amount: Enter PI FB for year 1
- Tech Support Percent of Effort: Enter % of effort from the "Justification of Personnel Budget"
- Tech Support Salary: Enter Tech salary for year 1 (this must be calculated as part of Supplies Budget – total supplies budget not to exceed \$25K)
- Tech Support Fringe: Enter Tech salary for year 1 (this must be calculated as part of Supplies Budget – total supplies budget not to exceed \$25K)
- Supplies: Enter amount (this must be calculated as part of Supplies Budget – total supplies budget not to exceed \$25K)
- Travel: Enter the amount (this must be calculated as part of Supplies Budget – total supplies budget not to exceed \$25K) *Note: a portion of this money must be set aside to attend the CCFA Advances in IBD Conference held in December.*

The completed budget page(s) for all requested years will need to be uploaded as an attachment in the attachment section provided.

**Justification of Personnel Budget \*Required**

Download the budget template from the form section of our web site and save to your hard drive. Complete budget page(s) then fill in the total budget for years one to three for PI and Technical Support. The budget pages will need to be uploaded as an attachment in the attachment section provided. It is the responsibility of the applicant to justify the role of the technical support staff.

**Letters of Support (Mentor) \*Required**

Attach supporting letter from your mentor(s). 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

**NIH Biosketch (Mentors) \*Required**

Attach the NIH Biosketch for all Mentor(s).

**Signature Page \*Required**

Download the signature templates from the form section of our web site and save to your hard drive. These forms need to be completed and uploaded on the attachment section provided. The forms can be found in the form section of the CCFA web site. The original signatures must be included in the paper (master) copy of the application sent to CCFA. Be sure to include signatures for the applicant, mentor(s), Department Director and Financial Officer authorized to commit the applicant institution to sponsoring the project supported by the award.

**Applicants Research Experience \*Required**

Download the template from the form section of our web site and save to your hard drive. Please follow the instructions to provide the following information:

- Education
- Experience
- Degree..... year conferred.....
- Explain any time lapses in work history
- Specialty or subspecialty board certification(s) held
- All your publications
- Academic professional honors
- Memberships in professional societies

**Applicants CV/NIH Biosketch \*Required**

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)
- Research Experience (see template in the form 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 Mentors Page- Optional**

Upload information on additional mentor(s), whom are not already listed on the main application.

**Resubmission Material \*Required if this is 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.).
- Scan and attach copies of the following
  - Critiques (Summary Statement) of the original application
  - Budget pages of previous application
  - Overall objectives and specific aims of previous application

Upload all documents to this section.

**References/ Appendices- Optional**

A letter from the applicant's department chairman guaranteeing protected research time commensurate with the percentage of effort/salary to be devoted to the research project.

Uploaded reference material may include, but not limited to:

- Article references
- Abstracts
- Original Pictures
- Other Letters of Support

Upload all reference material this can include, but not limited:

- Article references
- Abstracts
- Original Pictures
- Other Letters of Support

**Human and/or Animal Approvals- Optional**

Upload IRB approvals for human and animal research

**Abstract for Pending Applications- Optional**

Upload abstracts for all pending applications held by the Applicant. Please note: the titles and institution for which the applicant is awaiting approval should be listed on the electronic application under the Abstract section.

**Electronic Transfer- Optional:**

Download the template from the form section of our web site and save to your hard drive. Complete if, in the event of award, you would like to have payments made electronically.

**\*\*\*PLEASE FOLLOW THE INSTUCTIONS FOR NAMING ALL ATTACHMENTS\*\*\***

## **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 be completed and uploaded on the attachment section provided. The forms can be found in the form section of the CCFA web site.